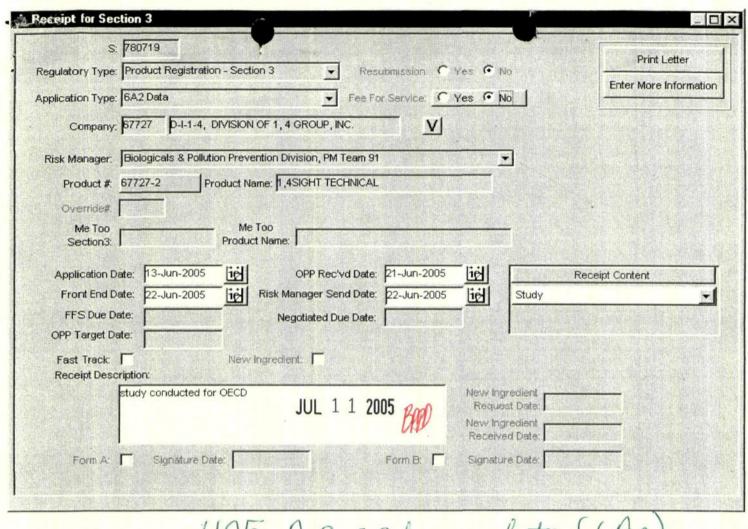
# EPA Jacket 67727-2 Vol.1



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A IO JUL 2 6 2005 Sal-2

Primary Recipient

\_\_\_Secondary Recipient

### MRID 465 77001 NOTICE OF RECEIPT OF 6(a) (2) SUBMISSION

DATE: 7/5/05

FROM: Information Services Branch

Information Resources and Services Division

o: Sheryl Reilly, PM 91

The 6(a)(2) Team has taken steps to get this screened by the appropriate science staff.

Screening determines the priority and timeframe for review.

As soon as screen results are received by ISB, you will be informed by your division 6(a)(2) Team representative. This information will determine instructions for review.

Please do not put this study or letter into review until you receive screen results and review instructions from your division 6(a)(2) Team representative.

If you have any questions, please contact Kathleen O'Malley. She is located in Room 224 CM2 and can be reached on 305-5411.

## FEE FOR SERVICE

## **MEMORANDUM**

DATE: 7/1/05

TO: Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: 

fully accepted submission

partially accepted submission

□ rejected submission



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 1, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

D-I-1-4, DIVISION OF 1, 4 GROUP, INC. PO Box 860
MERIDIAN, ID 83680-0860

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 21-JUN-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

465770-00

## Margery M. Exton

## Consultant Pesticide Regulatory Affairs

June 13, 2005

Document Processing Desk 6(a)2
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: 6(a)2 Submission - Study Conducted for OECD

To Whom It May Concern:

Enclosed please find three copies of a final report testing the active ingredient 1,4-Dimethylnaphthalene under an OECD Guideline for mutagenic activity. This report is being submitted on behalf of D-I-1-4, a division of 1,4Group, Inc. (EPA registrant number 67727). D-I-1-4 has filed an registration application with the European Union, and subsequent to their review, this study was requested above and beyond the data set supporting registration in the United States.

The mutagenic potential of 1,4-dimethylnaphthalene (1,4-DMN) was evaluated in a very sensitive *in vitro* cell assay, the Mouse Lymphoma Gene Mutation Assay. The low cytotoxicity expressed by 1,4-DMN required the use of relatively high doses in this study. As a result, the top three doses precipitated in the growth medium, as they were significantly above the solubility limit of 1,4-DMN. A positive response was obtained at only one dose, a dose that precipitated in the test system, and only in the presence of a metabolic activating system. A brief description of the test and the results follows.

In a preliminary dose range-finding/cytotoxicity determination, 1,4-DMN was shown to precipitate at a concentration of 333 ug/ml. However, because of its low cytotoxicity, the testing facility administered higher range-finding doses of up to 1000 ug/ml to obtain adequate cytotoxicity. Significant cytotoxicity was observed at 170 ug/kg and at all higher doses.

In the definitive test, 1,4-DMN was administered to cultured mouse lymphoma cells in the presence and absence of a metabolic activating system. In the absence of a metabolic activating system, no significant mutagenic activity was observed at any dose. Therefore 1,4-DMN did not express mutagenic activity in the absence of a rat liver metabolic activating system. Cell cultures that contained a metabolic activating system received doses of 0, 50, 75, 100, 150, 170, 200, 210,

or 220 ug/ml. Precipitation of the test substance was seen at doses of 150, 170, 200, and 220 ug/l.

A positive mutagenic response was obtained only at one dose level, 170 ug/ml. The doses below and above 170 ug/ml did not induce a significant mutation frequency. In fact, the higher dose of 200 ug/ml induced a mutation frequency just slightly higher than the control incidence.

While this positive response in the Mouse Lymphoma Assay is reportable under FIFRA Section 6(a)2, D-I-1-4 does not believe it has human health relevance. The positive response was only observed in the presence of a metabolic activating system, only a one dose (not the highest dose), and at a dose where substantial test substance precipitation was observed. In contrast, at the three doses which were soluble in the test system, significant cell mutation was not observed.

If you have any questions regarding the conduct of this study, please do not hesitate to contact me so I can facilitate communication with the European contacts. Thank you.

Sincerely,

Margery M. Exton

Enclosures

Transmittal
Final report, three copies

## TRANSMITTAL DOCUMENT FOR

#### DATA SUBMITTED IN SUPPORT OF 1,4Sight Technical EPA File Symbol 67727-2

1. Name and Address of Submitter:

D-I-1-4, a Division of 1,4Group, Inc. P.O. Box 860 Meridian, ID 83680

2. Regulatory Action in Support of Which This Package is Submitted:

6(a)2 submission - OECD Mutagenicity Study

3. <u>Transmittal Date:</u>

June 13, 2005

4. List of Submitted Studies:

MRID NUMBER

**46577001** Document 1

Evaluation of the Mutagenic Activity of 1,4-Dimethylnaphthalene in an In Vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells. OPPTS 870.5300. Verspeek-Rip, C.M. Notox B.V. Hambakenwetering 7, 5231 DD's-Hertogenbosch, The Netherlands. April 12,

2005. 29 Pages.

Company Official: Margery M.

Margery M. Exton, Agent of Record

Signature:

D-I-1-4, a Division of 1,4Group, Inc.

Contact Name and

Company Name:

Phone Number: Margery M. Exton, (703) 221-6639

## TRANSMITTAL DOCUMENT

#### FOR

#### DATA SUBMITTED IN SUPPORT OF 1,4Sight Technical EPA File Symbol 67727-2

1. Name and Address of Submitter:

D-I-1-4, a Division of 1,4Group, Inc. P.O. Box 860 Meridian, ID 83680

2. Regulatory Action in Support of Which This Package is Submitted:

6(a)2 submission - OECD Mutagenicity Study

3. Transmittal Date:

June 13, 2005

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MRID NUMBER

46577001 Docum

Document 1 Evaluation of the Mutagenic Activity of 1,4-

Dimethylnaphthalene in an In Vitro

Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells. OPPTS 870.5300. Verspeek-Rip, C.M. Notox B.V.

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Hertogenbosch, The Netherlands. April 12,

2005. 29 Pages.

Company Official: Ma

Margery M. Exton, Agent of Record

Signature:

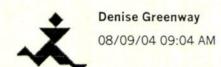
D-I-1-4, a Division of 1,4Group, Inc.

Contact Name and

Company Name:

Phone Number:

Margery M. Exton, (703) 221-6639



To: Rosemary Biancardi/DC/USEPA/US, andrew bryceland

cc:

Subject: data to route to the contractor for primary review (67727-2)

Hiya.

This is to inform you both that today I am placing on Rosemary's file room shelf data generated to meet international data requirements for technical 1,4-DMN (EPA Reg. No. 67727-2). For this reason, the data submitted on 7/12/2004 were designated as 6(a)(2), but the adverse effects screeners (K. O'Malley, W. Schneider, R. Jones, R. Gardner) have determined (or are expected to determine) that no expedited review is required; the data are to be handled normally.

Forwarded for primary review by the contractor are two data packages, as follows:

Decision No. 347258
Submission No. 764570
Data Package No. 306542 (5 eco tox volumes, MRIDs 463168-01 thru -05)
Data Package No. 306543 (1 90-day oral tox, rat, data volume; MRID 463168-06)

Please see me should there be questions or concerns.

Thanks for your help in routing and tracking this action.

Denise, 308-8263



Kathleen OMalley

08/09/04 08:46 AM

To: Denise Greenway/DC/USEPA/US@EPA

cc:

Subject: Re: 6A2 - BPPD Study Screens Needed (6) - MRID's 46316801-806

For 8/9/04 conversation's V/Bill + Kathleen, Bill will forward by Kathleen the screen sheek prepared by Pager + Russ when

expedit is required).

D. Greenway

Denise:

to Kathken the screen sheets prepared by Pager + Russ when those reviewers return to the office to finalize same. Data to be

Bill's note on the status of the 6(a)(2) screens for these studies is forwarded FYI. Will be glad to handled as discuss it with you in detail.

Kathleen

M. Kathleen O'Malley 6(a)(2) Team Information Resources & Services Division Office of Pesticide Programs USEPA (703) 305-5411

..... Forwarded by Kathleen OMalley/DC/USEPA/US on 08/09/2004 08:47 AM .....

William Schneider

To: Kathleen OMalley/DC/USEPA/US@EPA cc: Sheryl Reilly/DC/USEPA/US@EPA

08/05/2004 12:54 PM

Subject: Re: 6A2 - BPPD Study Screens Needed (6)

Roger Gardner did his on the tox study right away and found that no immediate action was needed. Russ Jones took the 5 eco screens but then he went on leave all this week (I wasn't aware of it ahead of time) and he won't be back until Tuesday. (Sheryl is also on leave now too). My preliminary discussions with Russ was that this shouldn't be a problem because the registered uses for the product evidently don't involve any environmental exposure. I'm reluctant to go with a decision on my own since Russ was the reviewer for this registration. Could you live with a "screen of the screen" preliminary decision that there shouldn't be a problem no matter what the eco studies showed since there wouldn't be an exposure? Then when Russ gets back we can confirm this?

Roger filled out the forms. Do you want the actual paperwork on that? Or how do you want to handle it.

Bill

Kathleen OMalley

- C

Kathleen OMalley

To: William Schneider/DC/USEPA/US@EPA

08/05/2004 12:12 PM

Subject: 6A2 - BPPD Study Screens Needed (6)

?

Bill:

Do you have any feedback on these screens yet? We are coming up on the 10 day screen period this weekend.

Thanks for your help!

Kathleen

M. Kathleen O'Malley 6(a)(2) Team Information Resources & Services Division Office of Pesticide Programs USEPA (703) 305-5411

---- Forwarded by Kathleen OMalley/DC/USEPA/US on 08/05/2004 12:13 PM -----



Kathleen OMalley

To: William Schneider/DC/USEPA/US@EPA

07/27/2004 02:26 PM

Subject: 6A2 - BPPD Study Screens Needed (6)



Bill:

Can you get these screens to me in 10 days? Would appreciate it so much!

MRID #46316801 - Closed Bottle Test (OECD 301D)

RE: 1,4-Dimethylnapthalene (RN: 67727-2 - 1,4Sight Technical):







46136801.wpd 46316800.ti(Transmittal for Studies) 46316801.tit

MRID #46316802 - 96 Hour Tox Test With Freshwater Alga (OECD 201) RE: 1,4-Dimethylnapthalene (RN: 67727-2 - 1,4Sight Technical):





46136802.wpd 46316802.tit

MRID #46316803 - 96 Hour Static Renewal Acute Tox: Fathead Minnow (OECD 203) RE: 1,4-Dimethylnapthalene (RN: 67727-2 - 1,4Sight Technical):





46136803.wpd 46316803.tif

MRID #46316804 - 7 Day Static Renewal Tox: Duckweed Lemna gibba G3 RE: 1,4-Dimethylnapthalene (RN: 67727-2 - 1,4Sight Technical):





46136804.wpd 46316804.ti1

MRID #46316805 - Analytical Method for Determination of Chemical in Algal Medium RE: 1,4-Dimethylnapthalene (RN: 67727-2 - 1,4Sight Technical):





46136805.wpd 46316805.ti1

MRID #46316806 - 90 Day Oral Dietary Toxicity in Rats: Amended Report RE: 1,4-Dimethylnapthalene (RN: 67727-2 - 1,4Sight Technical):





46136806.wpd 46316806.tit

Kathleen O'Malley 6(a)(2) Team Information Resources & Services Division Office of Pesticide Programs USEPA (703) 305-5411

Receipt for Section 3	
S: 764570  Regulatory Type: Product Registration - Section 3  Application Type: 6A2 Data  Company: 67727  D-I-1-4 INC	Print Letter Enter More Information
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91	
Product #: 67727-2 Product Name: 1,4SIGHT TECHNICAL	
Override#	
Me Too Section3:  Me Too Product Name:	
Application Date: 12-Jul-2004 OPP Rec'vd Date: 14-Jul-2004	Receipt Content
Front End Date: 14-Jul-2004 Risk Manager Send Date: 22-Jul-2004	
Fast Track: New Ingredient:	
Receipt Description:	
B(a)(2) Submission.  BLANCE 2 2 2004  New Ingredient Request Date:  New Ingredient Received Date:	
Form A: Signature Date: Form B: Signature Date:	

Caz data

red 8/6/04 from Andy. Linda agrees that an Monday

I should roote this to Bill. Keep Andy in formed gala

I think Bill will decide that HE not 602 + to review as a

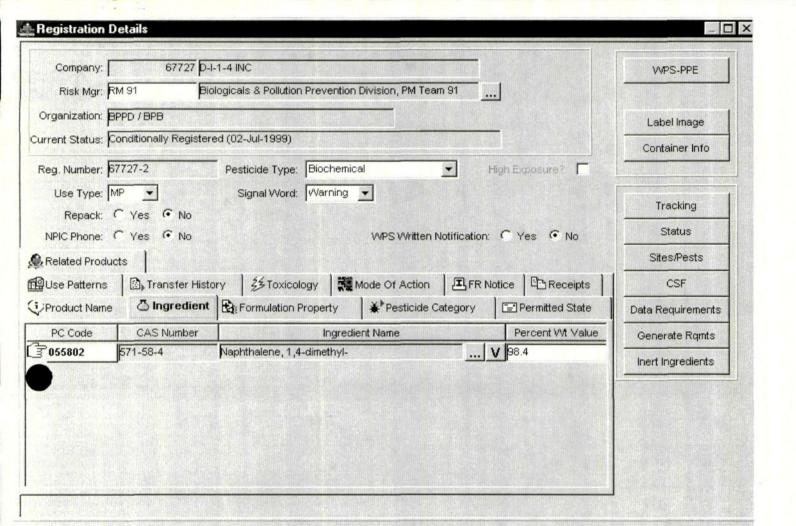
normal data set

s Roger has seen rat shely a said it should be reviewed. A IO

Andy 405

8/9/04 Bill says Roger has seen rat shuly & said it should be reviewed normally, in not expedited as 692. Russ was to have reviewed the others, but he is an leave. Bill + I agrad to so an + route to contractor for 10 12 view, ensure Roger & Russ receive studies for 20.

AUG 6 2004 Palh



## BPPD Screen Pacakge

Front End	(Team Leader Lind)	Hollis.	RAL. (Shi)	•
Product Name:	1 A Sight Tech	huical		
File Symbol No.	67727-2	_	□ FOOD	
Active Ingredient:	1,4 Dinet	hal pothale.	e Non-FOOD	
Date In BPPD:  Date To Screen Tes	7/22/04 am: 9/27/04	·	New Submi	
Package	(RAL	)		·
Pre-Registration (V	leetiag Miautes: 🗆 Yes 🖯	None .	•	
See Administrativ	e Material Checklist for in	formation and comm	nents on label, CSF, fo	ाताड, स्ट.
Comment:	·			
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Jacket: 🗌 Anache	ed. 🗀 Not Pr <del>es</del> ent for Scienc	e Screen		
Science Scr	een_			
Scientist:				
Administrative S	icreed: CPBS CFuil		·	
Science Screen:	Cras Cras			

# Data Screen Comment Form for Active Ingredients [1,4-Dimethylnaphthalene); PC No:055802] Product Name [1,4 Sight Technical; EPA File Symbol No.67727-2] Date [7/30/2004] RAL [Linda Hollis] Screener [Nasrin Begum]

Circle One: PASS

#### THIS FORM DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

#### **Product Chemistry**

No product chemistry data is submitted in this package.

#### **Toxicity**

Study (MRID463168-06) submitted to address data requirement appears to be adequate.

#### Non-target Organisms/ Environmental Fate

1. Studies (5) submitted to address data requirement appears to be adequate.

#### **Product Performance (Efficacy)**

Not present. Not required.

#### Residue

Not present. Not applicable.

#### Comments/Recommendations:

It is a 6(a) (2) submission (adverse effect). The relevant pages from the CFR are attached. The transmittal letter states that the registrant is filing a registration application to European Union (EU). The 6 studies submitted are the additional studies generated from testing 1,4-Dimethylnaphthalene to support registration at EU. My question is purpose for this submission to EPA.

At for AVG, just because date are await the should

be note a vail for over review. Callis the

#### § 159.165

products which arises in the course of litigation concerning the effects of such products, regardless of when the information is first acquired, provided that neither of the provisions of paragraphs (b)(3) or (b)(4) of this section are met. Such information shall be submitted in the same manner and according to the same schedules as it would have to be submitted by a current registrant of a pesticide product to which the information pertained.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

#### § 159.165 Toxicological and ecological studies.

Adverse effects information must be submitted as follows:

- (a) Toxicological studies. (1) The results of a study of the toxicity of a pesticide to humans or other non-target domestic organisms if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:
- (i) That is in a different organ or tissue of the test organism.
- (ii) At a lower dosage, or after a shorter exposure period, or after a shorter latency period.
- (iii) At a higher incidence or frequency.
- (iv) In a different species, strain, sex, or generation of test organism.
  - (v) By a different route of exposure.
- (2) Acute oral, acute dermal, acute inhalation or skin and eye irritation studies in which the only change in toxicity is a numerical decrease in the median lethal dose ( $LD_{50}$ ), median lethal concentration ( $LC_{50}$ ) or irritation indices, are not reportable under this part unless the results indicate a more restrictive toxicity category for labeling under the criteria of 40 CFR 156.10(h).
- (b) Ecological studies. The results of a study of the toxicity of a pesticide to terrestrial or aquatic wildlife or plants if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:
- (1) At levels 50 percent or more lower than previous acute toxicity studies with similar species, including determinations of the median lethal dose ( $LD_{50}$ ), median lethal concentration

(LC<sub>50</sub>), or median effective concentration (EC<sub>50</sub>).

- (2) At lower levels in a chronic study than previous studies with similar species.
- (3) In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10 percent or less of the lowest  $LC_{50}$  or  $LD_{50}$  for a similar species.
- (4) For plants when tested at the maximum label application rate or less, if either of the following conditions is met:
- (i) More than 25 percent of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(11) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(c) Results from a study that demonstrates any toxic effect (even if corroborative of information already known to the Agency), must be submitted if the pesticide is or has been the subject of a Formal Review based on that effect within 5 years of the time the results are received. Within 30 calendar days of the publication of a Notice of Commencement of a Formal Review in the FEDERAL REGISTER, all information which has become reportable due to the commencement of the Formal Review must be submitted.

(d) Incomplete studies. Information from an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which would otherwise be reportable under paragraphs (a), (b) or (c) of this section must be submitted if the information meets any one of the following three sets of criteria:

- (1) Short-term studies. A study using a test regimine lasting 90 calendar days or less, and all of the following conditions are met:
  - (i) All testing has been completed.
- (ii) A preliminary data analysis or gross pathological analysis has been conducted.
- (iii) Final analysis has not been completed.

(iv) A reasonable period for completion of the final analysis not longer than 90 calendar days following completion of testing has elapsed.

(v) Comparable information concerning the results of a completed

study would be reportable.

(2) Long-term studies. A study using a test regimine lasting 90 calendar days or less, and all of the following conditions are met:

(i) All testing has been completed.

(ii) A preliminary data analysis or gross pathological analysis has been conducted.

(iii) Final analysis has not been completed.

(iv) A reasonable period of completion of final analysis (not longer that 1 year following completion of testing) has elapsed.

(v) Comparable information concerning the results of a completed

study would be reportable.

(3) Serious adverse effects. Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substances tested, because the effects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation, and 30 days have passed from the date the registrant first has the information.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998]

#### §159.167 Discontinued studies.

The fact that a study has been discontinued before the planned termination must be reported to EPA, with the reason for termination, if submission of information concerning the study is, or would have been, required under this part.

### § 159.170 Human epidemiological and exposure studies.

Information must be submitted which concerns any study that a person described in §159.158(a) has concluded, or might reasonably conclude, shows that a correlation may exist between exposure to a pesticide and observed

adverse effects in humans. Information must also be submitted which concerns exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

### §159.178 Information on pesticides in or on food, feed or water.

(a) Food and feed. Information must be submitted if it shows that the pesticide is present in or on food or feed at a level in excess of established levels, except that information on excess residues resulting solely from studies conducted under authority of FIFRA section 5 or under other controlled research studies conducted to test a pesticide product need not be submitted, provided that the treated crop is not marketed as a food or feed commodity. The information to be submitted is the same as that required in §159.184(c)(1), (2), (3), and (4)(iv)(E), (F), (G), and (H).

(b) Water. (1) Information must be submitted if it shows that a pesticide is present above the water reference level in any of the following instances:

(i) Waters of the United States, as defined in §122.2 of this chapter, except paragraph (d) of §122.2.

(ii) Ground water.

(iii) Finished drinking water.

(2) If the lowest detectable amount of the pesticide is reported, the detection

limit must also be reported.

(3) Information need not be submitted regarding the detection of a pesticide in waters of the United States or finished drinking water if the pesticide is registered for use in finished drinking water or surface water and the amount detected does not exceed the amounts reported by a registrant in its application for registration, as resulting in those waters from legal applications of the pesticide.

(4) Information need not be submitted concerning detections of pesticides in waters of the United States, ground water or finished drinking water if the substance detected is an inert ingredient, or a metabolite, degradate, contaminant or impurity of



## U.S. Environmental Protection Agency

## Pesticides: Regulating Pesticides

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Restricted & Canceled

Pesticide Tolerances

Registration Information Sources

## Adverse Effects Reporting: FIFRA 6(a)(2)

Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide product registrants to submit adverse effects information about their products to the EPA. The following regulations and guidance documents have been published which provide registrants details on what, when and how to report this information.

#### Addresses to Use When Submitting Information

Registrants' 6(a)(2) submissions through the U.S. mail must be mailed to the following address:

Document Processing Desk -6(a)(2) Office of Pesticide Programs- 7504C U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, DC 20460-0001

Registrants' 6(a)(2) submissions via courier service must be addressed as follows:

Document Processing Desk - 6(a)(2) Office of Pesticide Programs Crystal Mall #2, Rm. 266A 1801 South Bell Street Arlington, VA 22202-4501

#### Federal Register Notices

Final 6(a)(2) Regulations – September 19, 1997 (62 FR 49369) -The regulations describe the various types of adverse effects information and specify how and when to submit the information. The preamble discusses all the comments that were received during the rule-making process and the decisions that EPA made on each issue. The final regulations serve as the foundation for the entire regulatory program.

Technical Corrections to 6(a)(2) Regulations – June 19, 1998 (63 FR 33580) - This notice corrected the definition of registrant that appeared in the September 19, 1997 regulations and thereby narrowed the reach of the 6(a)(2) regulations. It also clearly established time frames for reporting the various types of adverse effects information and specified the information to be submitted about incidents.

Deferral of Compliance Date – August 3, 1998 (63 FR

41192) – This notice sets August 17, 1998 as the date when registrants must begin to comply with the new regulations. This supersedes the original effective date of the regulations which was June 16, 1998.

Notice of Class Determination 1-99 - Disclosure of Adverse Effects Information – December 15, 1999 (64) FR 70019) - On September 28, 1999, EPA issued Class Determination 1-99 regarding disclosure of adverse effects information submitted under FIFRA section 6(a)(2). Notice of its availability was published in the Federal Register on December 15, 1999. Class Determination 1-99 (203 KB, PDF) establishes certain information submitted under 6(a)(2) as a class. It states that the provisions in FIFRA section 10(d)(1) regarding safety and efficacy information apply to adverse effects information submitted under 6(a)(2). The class determination affirms that with the exception of information that discloses manufacturing processes, methods for detecting inert ingredients, or the identity of inert ingredients (provisions of 10(d)(1)(A), (B), and (C)), safety and efficacy information is not entitled to confidential treatment.

#### **Pesticide Registration Notices**

PR Notices are formatted in Adobe's Portable Document Format (PDF).

PR Notice 98-3 – Guidance on Final FIFRA Section 6(a) (2) Regulations for Pesticide Product Registrants – April 3, 1998 – PRN 98-3 provides registrants guidance on a number of questions and issues raised after the regulations were published. Topics addressed include role of agents, aggregate reporting of incidents, expanded definitions of incident severity categories, waiver requests, and property damage incidents. (72 KB, PDF)

PR Notice 98-4 – Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants – August 4, 1998 – PRN 98-4 provides registrants guidance on additional questions and issues. These include issues addressed in the technical corrections such as definition of registrant, reporting timeframes, and required information. It also dropped the requirement to report incidents in which an adverse effect has not occurred but may occur in the future. (31 KB, PDF)

PR Notice 2000-8 - Reportability of Attorney's Opinions and Conclusions under 40 CFR Part 159 and FIFRA Section 6(a)(2)

PRN 2000-8 informs registrants of EPA's opinion that an attorney's professional legal judgment is not an opinion or conclusion that is reportable under 40 CFR part 159. Opinions and conclusions of attorneys other than the attorney's professional legal judgment can be reportable

under part 159. Factual information upon which an attorney's professional legal judgment is based must be reported if it meets the criteria of part 159.

#### **Related Information**

Voluntary Incident Reporting Forms and Instructions

ENTI disclaimer▶ — A work group comprising
representatives of registrant companies and trade
associations designed forms and instructions for
capturing and submitting incident reports. EPA staff
provided input to the process. Use of the forms is
voluntary and information submitted using the forms will
be accepted by the Agency. Other formats that meet the
requirements of the regulations will be acceptable to the
Agency as well.

Code of Federal Regulations – 40 CFR, Chapter I, Part 159, Sub-Part D - Reporting Requirements for Risk/Benefit Information - Revised as of July 1, 2002. EXIT disclaimer➤ - The Code of Federal Regulations codifies the 6(a)(2) regulations that were published in the Federal Register notices listed above. It integrates the language in the September 19, 1997 regulations with the technical corrections published on June 19, 1998. As a result, this presentation of the regulations is much easier to work with than the separate Federal Register notices. 40 CFR does not, however, include the preambles to the regulations that were part of the Federal Register notices. The preambles explain the bases for the Agency's decisions on the various issues raised by the regulatory program and provide insights which may be valuable to the public.

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Last updated on Thursday, July 22nd, 2004 URL: http://www.epa.gov/pesticides/fifra6a2/

Primary Recipient

\_\_\_Secondary Recipient

## MRID 46316801 - 46316806 NOTICE OF RECEIPT OF 6(a) (2) SUBMISSION

DATE: 7/21/04

FROM: Information Services Branch

Information Resources and Services Division

TO: Sheylikeilly, BPPD

The 6(a)(2) Team has taken steps to get this screened by the appropriate science staff.

Screening determines the priority and timeframe for review.

As soon as screen results are received by ISB, you will be informed by your division 6(a)(2) Team representative. This information will determine instructions for review.

Please do not put this study or letter into review until you receive screen results and review instructions from your division 6(a)(2) Team representative.

If you have any questions, please contact Kathleen O'Malley. She is located in Room 224 CM2 and can be reached on 305-5411.



## **MEMORANDUM**

DATE: 07/20104

BPPD (91), Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately two weeks from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: A fully accepted submission

□ partially accepted submission

□ rejected submission



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 15, 2004

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

D-I-1-4 INC 3719 THOMASSON CROSSING DRIVE TRIANGLE, VA 22172

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-JUl-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

## Margery M. Exton

Consultant Pesticide Regulatory Affairs

#### FAX TRANSMISSION COVER SHEET

Date: July 19, 2004

To: Kathleen O'Malley

Fax: (703) 305-7670

Re: Flagging Statement for 90-day Study

YOU SHOULD RECEIVE 2 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL (703) 221-6639.

Dear Kathleen -

I've returned from vacation, and am attaching a flagging statement page, to be inserted as the fourth page (3A) for the 1,4-Dimethylnaphthalene 90-day report, as you requested. The contract lab thought we only needed that if we submitted it to support a new or amended U.S. registration, or in response to a DCI. I apologize for the inconvenience and delay.

In reviewing the flagging criteria under 158.34, the report does not meet codes 1 - 4, since neoplasms were not an effect seen in this study. It doesn't meet code 10, since cholinesterase inhibition was not observed. While there were target organ effects in the kidney, code 11 benchmarks it against a current ADI. 1,4-Dimethylnaphthalene has an exemption from the requirement of a tolerance, so there is no ADI set by EPA at this time.

Please let me know if you need anything else to get this through to the appropriate toxicology reviewer. I'll be in all week. Have a good day!



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 15, 2004

D-I-1-4 INC 3719 THOMASSON CROSSING DRIVE TRIANGLE, VA 22172

Report of Analysis for Compliance with PR Notice 86-5

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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7/19/04.

7/13/04 - Outog

Thank you for your submittal of 14-JUL-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [06]:

\* You must include the appropriate flagging statement for this study as specified in 40 CFR 158.34. This statement must be signed and dated by an authorized representative of the company.

## Margery M. Exton

463168-00

Consultant
Pesticide Regulatory Affairs

July 12, 2004

Document Processing Desk 6(a)(2)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Possible 6(a)(2) Submission -- Studies Conducted for OECD

To Whom It May Concern:

Enclosed please find six final reports testing the active ingredient 1,4-Dimethylnaphthalene under various OECD Guidelines. These reports are being submitted on behalf of D-I-1-4, Inc. (EPA registrant number 67727). D-I-1-4 is filing a registration application with the European Union this month, and these studies were requested above and beyond the data set supporting registration in the United States. The Agency may not consider all of these reports as meeting the FIFRA 6(a)(2) regulations at 159.165 as some show little or no adverse effect, but were either conducted with a different test organism or under a protocol not required by EPA. These reports constitute all of the additional testing generated by D-I-1-4 to support registration in the European Union. Please contact me at the address below if you would like to discuss this submission.

Sincerely,

Margery M. Exton

Agent of Record, D-I-1-4, Inc.

Enclosures

Transmittal

Six Final reports (3 copies each)

# TRANSMITTAL DOCUMENT FOR DATA SUBMITTED IN SUPPORT OF 1,4Sight Technical EPA FILE SYMBOL 67727-2

1. Name and Address of Submitter:

D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680

2. Regulatory Action in Support of Which This Package is Submitted:

Possible 6(a)(2) Reporting - Studies Conducted for OECD

Document 1

3. Transmittal Date:

July 12, 2004

4. List of Submitted Studies:

MRID NUMBER

46316801

	Document 1	Test. OECD 301D. Schaefer, E. and Siffiqui, A. Wildlife International, Ltd. 8598 Commerce Drive, Easton, Maryland 21601. Sept. 26, 2002. 28 Pages.				
46316802	Document 2	1,4-Dimethylnaphthalene: A 96-Hour Toxicity Test with the Freshwater Alga (Selenastrum capricornutum). OECD 201 Desjardins. D., Van Hoven, R., and Krueger, H. Wildlife International, Ltd. 8598 Commerce Drive, Easton, Maryland 21601. July 29, 2002. 51 Pages.				
46316803	Document 3	1,4-Dimethylnaphthalene: A 96-Hour Static-Renewal Acute Toxicity Test with the Fathead Minnow (Pimephales promelas). OECD 203. Palmer, S., Van Hoven, R.,				

1,4-Dimethylnaphthalene: Closed Bottle

and Krueger, H. Wildlife International, Ltd. 8598 Commerce Drive, Easton, Maryland

21601. Aug. 22, 2002. 42 Pages.

46316804	Document 4	1,4-Dimethylnaphthalene: A 7-Day Static-Renewal Toxicity Test with Duckweed (Lemna gibba G3). Desjardins. D., Van Hoven, R., and Krueger, H. Wildlife International, Ltd. 8598 Commerce Drive, Easton, Maryland 21601. Aug. 7, 2002. 46 Pages.
46316805	Document 5	Analytical Method Verification for the Determination of 1,4-Dimethylnaphthalene in Algal Medium. OECD Special Study. Van Hoven. R., and Nixon, W. Wildlife International, Ltd. 8598 Commerce Drive, Easton, Maryland 21601. June 24, 2002. 38 Pages.
46316806	Document 6	90-Day Oral (Diet) Toxicity Study of 1,4-Dimethylnaphthalene in Rats. OECD 408/OPPTS 870.3100. Mallett, E. Experimur, 2929 South Ellis Avenue, Dreyfus Building, Suite 600, Chicago, Illinois 60616. March 10, 2004. 381 Pages.

Company Official: Margery M. Exton. Agent of Record

Signature:

Company Name: D-I-1-4, Inc.

**Contact Name and** 

Phone Number: Margery M. Exton, (703) 221-6639

## Margery M. Exton

463168-00

Consultant
Pesticide Regulatory Affairs

July 12, 2004

Document Processing Desk 6(a)(2)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

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Agent of Record, D-I-1-4, Inc.

Enclosures

Transmittal

Six Final reports (3 copies each)

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1. Name and Address of Submitter:

D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680

2. Regulatory Action in Support of Which This Package is Submitted:

Possible 6(a)(2) Reporting - Studies Conducted for OECD

3. Transmittal Date:

July 12, 2004

4. List of Submitted Studies:

MRID NUMBER

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Company Official: Margery M. Exton. Agent of Record

Signature: Mayler Exton

Company Name: D-I-1-4, Inc.

Contact Name and

Phone Number: Margery M. Exton, (703) 221-6639

# =BPPIPPRAT ACTION COPING FORM=

REGISTRANT/COMPANY NAME:	Fast Track: Yes No
D-1-1-4 Fnc	Reviewer Many
	Assigned by LH 1.29
EPA REG./FILE SYMBOL 67727-	(Note: If Fast Track, you may
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BPPD RECEIVED DATE 1/15/03	www.
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D-I-1-4, Inc., 1,4Si	ght Technical			90					
5. Name and Address of Ap D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680-		ode)		(b)(i), n to: EPA f	ny product Reg. No	is sim	ilar or ider	ntical in co	n FIFRA Section 3(c)(3) omposition and labeling
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Name Margery M. Exton			Agent of	Record				(703) 22	e <b>No. (Include Area Code)</b> 1-6639
I certify that the state I acknowledge that an both under applicable	y knowlinglly false or		all attachn					The state of the s	6. Date Application Received (Stamped)
2. Signature	2 Euto -	)	3. Title Agent of F	Record					

5. Date

4. Typed Name

Margery M. Exton

12-18-0002



······································	By Weight
Active Ingredient: 1,4-Dimethylnaphthalene*	98.4%
Other Ingredients:	1.6%
TOTAL	100.0%
* Contains 8.3 pounds active ingredient per gallon.	

# Keep Out of Reach of Children WARNING

Complies With EPA
Accepted Labeling Dated \_\_\_\_\_

PRECAUTIONARY STATEMENTS

Daviewed By

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
lf swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

**Emergency Information** 

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See Directions for Use on Reverse
Net Contents \_\_\_\_\_

Manufactured For: D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA

EPA Reg. Number 67727-2 EPA Est. Number 68738-JPN-001 Product of Japan Revision 012202-A



#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

#### PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

#### PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

#### CONTAINER DISPOSAL

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

#### CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



	• • • • • • • • • • • • • • • • • • • •	By Weight
Active Ingredient:	1,4-Dimethylnaphthalene*	98.4%
Other Ingredients:		1.6%
TOTAL		100.0%

# Keep Out of Reach of Children WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination

waters unless in accordance with the requirements of a National Pollutant Discharge Elimination
System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do
not discharge effluent containing this product to sewer systems without previously notifying the local
sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of
the EPA.

See Directions for Use on Reverse
Net Contents \_\_\_\_\_

Manufactured For: D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA EPA Reg. Number 67727-2 EPA Est. Number 68738-JPN-001 Product of Japan Revision 012202-A

<sup>\*</sup> Contains 8.3 pounds active ingredient per gallon.



#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

#### PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

#### PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

#### CONTAINER DISPOSAL

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

#### CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

## 1,4SIGHT® TECHNICAL

#### Aerosol Grade - Plant Growth Regulator

			By Weight
Active Ingredient:	1,4-Dimethylnaphthalene*		98.4%
Other Ingredients:		······································	1.6%
TOTAL		······································	100.0%
* Contains 8.3 pounds	active ingredient per gallon.	32 AFG AGG FOR IN	C) Fritz Darie and

## Keep Out of Reach of Children WARNING

JAN 22 2002

PRECAUTIONARY STATEMENTS

Under the Federal Insecticides, Pangicide, and Rodenticide Act. as amanded, for the posticide Hazards to Humans and Domestic Animals Epis Reg. No. 6772

ACCEPTED

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing

before reuse.

First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
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> See Directions for Use on Reverse **Net Contents**

Manufactured For: D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA

EPA Reg. Number 67727-2 EPA Est. Number 68738-JPN-001 Product of Japan Revision 1

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

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# JAN 22 2002

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-	12
-	17

Margery M. Exton 3719 Thomasson Crossing Drive Triangle, VA 22172

Subject:

1,4Sight® Technical

EPA Reg. No. 67727-2

Your Correspondence of December 5, 2001 and January 2, 2002

Dear Ms. Exton:

On the behalf of your client, D-I-1-4, Inc., you responded to the Agency's October 25, 2001, letter with the submission of a revised label. Subsequently, at Denise Greenway's telephoned request, you furnished by e-mail on January 2, 2002, a replacement for the label's first page (to correct the EPA Establishment Number).

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you:

- 1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
- 2. Submit three (3) copies of your final printed labeling before releasing the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags, or drum labels.

CONCURRENCES								
SYMBOL >	7511C	7511C	75710	7511C				
SURNAME	Greenway	Toshrol	Hallis	Rill				
DATE >	1/14/02	1/14/02	1.17.02	1/22/02	/			43
EPA Form 1320-	1 (12-70)	1		, ,		OFF	CIAL FILE COPY	

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Should you have questions or concerns regarding this letter, please contact me or telephone Denise Greenway on (703) 308-8263.

Sincerely,

Sheryl K. Reilly, Ph.D.

Chief

Biochemical Pesticides Branch Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

DGreenway/308-8263/1-11-02/67727-2amend.wpd/14DMN



**Denise Greenway** 

01/11/02 07:51 AM

To: Freshteh Toghrol/DC/USEPA/US@EPA

cc:

Subject: updated page 2 of 9/13/01 1,4-DMN memo

FT,

Here's the file, which I updated by replacing the page 2 item 2 values with those from page 29 of 54 from MRID 453771-02. I will place a hard copy of just the corrected page on your file room shelf so that you might update any paper records you may have. My electronic files are updated, and I will also insert the corrected page in the jackets (67727-1, -2, -3 and -4), as well as in the BPPD chron file. If there are other locations requiring the update, please inform me.

Thanks for your help.

DG



#### \*Personal privacy information\*

**Denise Greenway** 

To: "Margery M. Exton"

01/03/02 07:52 AM

Subject: Re: Two replacement sheets for the 1,4-DMN labels

Good morning, Margery

I've checked the two label pages sent as the attachment to your e-mail of yesterday. While the one for 67727-2 is fine, missing text is a problem for the 67727-4 replacement page. The last line of text is absent from the boxed area ("...properly. Follow the "Directions...").

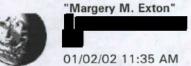
Could you please send (e-mail or fax) a corrected version? Thanks!

I still haven't received the study blowback, but will alert you ASAP to any CSF revision guidance for 67727-3.

Denise

fax: 703 305-0118

"Margery M. Exton"



To: Denise Greenway/DC/USEPA/US@EPA

cc:

Subject: Two replacement sheets for the 1,4-DMN labels

Hi Denise. Attached in wordPerfect format are the two replacement pages needed for the 1,4-DMN labels.

They are in the same file, and the first page is the Technical label with 6 replacing the 0 in the establishment number, and the second page is the 1,4Ship label with 4 replacing the \* in the registration number. I apologize for these errors and appreciate the chance to submit the corrections.

If these don't print out properly for you, email me back your fax number and I'll get them to you that way.

I await your call on how to amend the CSF. Thanks - Margery

Denise replacement sheets.W

på je reeded for -2 within

## 1,4SIGHT® TECHNICAL

#### Aerosol Grade - Plant Growth Regulator

		By Weight
Active Ingredient:	1,4-Dimethylnaphthalene*	98.4%
Other Ingredients:		1.6%
TOTAL		100.0%
* Contains 8.3 pounds	active ingredient per gallon.	

# Keep Out of Reach of Children WARNING

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

#### **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See Directions for Use on Reverse Net Contents

Manufactured For: D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA EPA Reg. Number 67727-2 EPA Est. Number 68738-JPN-001 Product of Japan Revision 1

Use this -2 mplacement page
along wingshild
other pages 1/2/12

## Labeling To Be On Can 1,4SHIP<sup>™</sup>

		Weight
Active ingredient:	1,4-Dimethylnaphthalene*	63.8%
Other ingredients:		36.2%
TOTAL		100%
* Contains 3.83 ounces	active logredient per can.	

EPA Reg. Number 67727-4

Follow the Directions for Use as labeled on the outer carton when applying this product.

# Keep Out of Reach of Children WARNING

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. May be harmful if inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Avoid breathing spray mist or vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in <u>Eyes</u>: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If <u>Swallowed</u>: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on <u>Skin or Clothing</u>: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

<u>If Inhaled</u>: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

#### **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

#### Physical or Chemical Hazards

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used

groperly follow the "D for" In this labe very carefully

# HIGHLY FLAMMABLE INGREDIENT INGREDIENTE ALTAMENTE INFLAMABLE

FBPPD PRAT ACTION CODING FORM rod 1/2/02
PM 90: Janet Andersen

REGISTRANT/COMPANY NAME: PESFICIOLE REGULATORY Affaires	Fast Track: Yes No X Reviewer Denke Greening Assigned by LAH
EPA REG./FILE SYMBOL 67727-2  ACTION CODE 346	[Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]
(New A.I/EUP'S/Tolerances: Yes□ No□)	AMENDMENT Label Changes per
BPPD RECEIVED DATE 12 18 01	125/01 Lt.
SUBMISSION BARCODE <u>\$ 407952</u> + \$60918	7
ASSIGNED IN PRAT: Yes No Date 12/28	
RAL RECEIVED DATE COMPLETED	LETED BY
(RAL initials)	, a,
FINAL ACTION  RESPONSE CODE:	
RESPONSE CODE:	
MOS:(1) Cite All CRP(4) Not Applicable Restricted Use:(8) Selective Manufacturing Use: Exclusive Use:	Yes No Yes No Yes No

## Margery M. Exton

### Consultant Pesticide Regulatory Affairs

December 5, 2001

Denise Greenway
PM Team 90
Biopesticides and Pollution Prevention Division (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Resubmission on 1,4-DMN Products in Response to Agency 10/25/2001 Letter

Dear Ms. Greenway:

Thank you for your thorough review of the D-I-1-4, Inc. submission in March of this year regarding amendment of the 1,4-DMN products. In response to the Agency letter of 10/25/2001, please find enclosed revised labels and confidential statements of formula incorporating the changes specified.

Additionally, the Agency questioned the use of the words "Made in Japan" on the various labels, in connection with the EPA establishment numbers indicated U.S.-based establishments. I have conferred with D-I-1-4's environmental attorneys on this issue, and supply the following information in the hopes of clarifying this issue.

The 1930's Tariff Act requires all products to bear a marking reflecting the product's country of origin. This law, and subsequent regulations, are enforced by the U.S. customs officers. For pesticide products, the regulations and policies have prescribed that the country of origin statement refer to the active ingredient's country of origin, and not to the origin of the inert (or other) ingredients. This is the case for all pesticides, regardless of the percentage of active ingredient within any given formulation. Hence, for all 1,4-DMN products, they must currently bear a statement reflecting Japan as the country of origin at this time.

Under the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA), registrants are required to ensure their products bear the establishment number of the final facility which actually produced the registered material. Since FIFRA defines the registered product as a function of not only a particular formulation, but the particular packaging and labeling as well, the appropriate establishment number for a product to bear is the one at which the registered material is produced (even if that only involves re-packaging and labeling of an existing formulation).

Furthermore, under 40 CFR 156.10(f) and as reflected in chapter 17 of the Label Review Manual, a registrant may have more than one establishment capable of producing a registered pesticide. For EPA labeling review, my preference is to show the establishment number of the facility which will most often be reflected on labeling in the market, rather than leave the establishment number off the EPA stamped label.

While D-I-1-4 imports 1,4-DMN from Japan, the packaging and labeling of the registered end-use products is currently done within the Country. Consequently, these products should bear both the statements reflecting Japan as the country of origin, and U.S.-based establishment numbers. I have discussed this subject with D-I-1-4, and am revising the enclosed labels to reflect their current practice.

Having said all of the above, I am also changing the country of origin marking to the words "Product of Japan", rather than "Made in Japan." Both statements are acceptable under the Tariff Act. However, this is the current industry trend, as it is thought to be less confusing than "Made in..." with respect to pesticides. There is no requirement to bear indications as to the country of origin of the various non-pesticidal ingredients within pesticide products, and "Made in..." can be easily construed to reflect the entire product.

Thank you for giving me the opportunity to clarify this situation, and to reflect D-I-1-4's current practice on the enclosed labeling. If you wish to discuss this subject further, please contact me on (703) 221-6639.

Submitted in support of this application, please find the following documents:

1,4Sight Technical1,4SeedApplication form 8570-1Application form 8570-1Revised labeling, 5 copiesRevised labeling, 5 copiesRevised CSE, 1 copy

Revised CSF, 1 copy

1,4Sight
Application form 8570-1
Revised labeling, 5 copies
Revised CSF, 1 copy

1,4Ship Application form 8570-1 Revised labeling, 5 copies Revised CSF, 1 copy

Sincerely,

Margery M. Exton

Pesticide Regulatory Consultant

Please read instructions on reverse before completing form.	Form Ap	proved. OMB No. 2070-00	60. Approval expires 2-28-95
United States  Environmental Protection  Washington, DC 20-		Registration  Amendment Other	OPP Identifier Number
Application	on for Pesticide - Sec	tion I	
1. Company/Product Number 67727-2	2. EPA Product Mar D. Greenway		Proposed Classification  None Restricted
4. Company/Product (Name) D-I-1-4, Inc./ 1,4Sight Technical	<b>PM#</b> 90		]
5. Name and Address of Applicant (Include ZIP Code) D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680-0860  Check if this is a new address	(b)(i), my product to:	veiw. In accordance with is similar or identical in co	omposition and labeling
	Section - II		
Amendment - Explain below.  Resubmission in response to Agency letter dated 10/2  Notification - Explain below.  Explanation: Use additional page(s) if necessary. (For section	Final printe Agency let "Me Too" Other - Exp	ed labels in repsonse to ter dated Application. Dlain below.	
	Section - III		
1. Material This Product Will Be Packaged In:	T		
Child-Resistant Packaging  Yes No  Certification must be submitted  Unit Packaging  Yes No  No. per Container	Water Soluble Packaging  Yes  No  If "Yes"  Package wgt  No. per  containe	2. Type of Containe  Metal Plastic Glass Paper Other (	
3. Location of Net Contents Information 4. Size(s) Ret	tail Container	5. Location of Label Directi	ons
6. Manner in Which Label is Affixed to Product Lithog Paper Stenci	glued iled	r	
	Section - IV		
1. Contact Point   Complete items directly below for identification	n of individual to be contacted,	if necessary, to process this	s application.)
Name Margery M. Exton	Title Agent of Record	Telephon (703) 22	ne No. (include Area Code) 1-6639
Certifica  I certify that the statements I have made on this form and I acknowledge that any knowlingly false or misleading sta both under applicable law.	all attachments thereto are true		6. Date Application Received (Stamped)
Mayor Extra	3. Title Agent of Record		:
4. Typed Name Margery M. Exton	12-5-200	1	53

SEPA	Environmenta	United States		Form Appro	~	OMB No. 20 Registrat Amendm Other	ion	OPP Ident	expires 2-28- tifier Number
		Application	n for Pestic	ide - Secti	on l				
1. Company/Product Num 67727-2	nber			Product Manage	er			Proposed Clas	sification Restricted
4. Company/Product (Na D-I-1-4, Inc./ 1,4Sigl			<b>PM#</b> 90					None	Restricted
D-I-1-4, Inc. P.O. Box 860 Meridian, ID 8368	Applicant (Include ZIP Co 0-0860 this is a new address	ode)	(b)(i), to: EPA	edited Reveny product is Reg. No	simi	lar or identic	al in o	composition	and labeling
			Section -	II					
Notification - Expl	esponse to Agency letter			Final printed I Agency letter "Me Too" Ap Other - Explai	date plicat	tion.	0		
			Section - I	li .	-				
1. Material This Product	Will Be Packaged In:						-		
Child-Resistant Packaging Yes No Pertification must be submitted	Yes No	No. per container	Water Soluble F Yes No If "Yes" Package wgt	No. per container			Metal Plastic Glass Paper		
3. Location of Net Conten	nts Information	4. Size(s) Reta	ail Container	5	Loca	ation of Label	Direct	tions	
6. Manner in Which Label		Lithogr Paper of Stencil	aph glued	Other	_				_
5 1 A 7 THE STATE OF THE STATE			Section - I	V					
1. Contact Point (Comple	ete items directly below f	or identification			neces	sary, to proce	ss th	is application.)	
Name Margery M. Exton			Title Agent of Record					ne No. (Includ 21-6639	e Area Code)
	atements I have made on any knowlinglly false or ole law.		all attachments th					6. Date App Received (Star	
2. Signature Mayor	& Ech		Agent of Record						
4. Typed Name Margery M. Exton		5	. Date						

12-5-2001

# 1,4SIGHT® TECHNICAL

	1,4SIGHT® TECHNICAL  Aerosol Grade - Plant Growth Regulator	&PPROV	
Other Ingredients:	1,4-Dimethylnaphthalene*	By Weight 87 98.4% 1.6% 100.0%	C COPY
	active ingredient per gallon.		

## Keep Out of Reach of Children WARNING

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
lf on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Emergency Information

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic\invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

> See Directions for Use on Reverse Net Contents

Manufactured For: D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA

"6" is correct replacement EPA Reg. Number 67727-2 EPA Est, Number 08738-JPN-001 Product of Japan Revision 1

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

#### PESTICIDE STORAGE

• Keep container closed. This product temporarily inhibits germination of seed potatoes.

#### PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

#### **CONTAINER DISPOSAL**

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

#### **CONDITIONS OF SALE**

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



\*Personal privacy information\*

**Denise Greenway** 

12/14/01 10:49 AM

To:

Subject: in receipt

cc:

Margery,

Thanks for the courtesy copy of the D-I-1-4 response to the Agency's 10/25/01 letter. I must say that the Branch may, upon receipt, route the official submission left at the document processing desk to a new fast track team (instead of routing it to me). However, I would be available to assist in the review, if needed. I did skim the cover letter regarding the research you performed to address the product country- of-origin and EPA Establishment No. issue. That background will be valuable; thank you for including it.

Thank you also for the beautiful holiday card, and for the candy. I am enjoying them both!!

I'm sorry that I missed your visit, and hope that you and your family have a safe and festive holiday season.

Denise

67727-1 OK

67727-3 (ask=+)

I checked the 10/25/01 letter and all of the 67727-4
requested changes are minor. They are few
in number: Try to act on this vising the
courtesy copy, before the official one arrives.
Then alert Fast Track Team. > FTT not involved

ck against last submission of lauds (3/28/01)

12/26 - left VM re 2 latel pages for ME Com out and man

67727-1 requested changes were made - MSD: changed from Japonico toldaho Est. + from Made in to Product of Japan OK

67727-2 regrested changes were make - ALCO, gave explanation the Est No line. Changed this tech products est No Extended the decided product to a Japanese are which is the but = 11 abilitient than previously used for another product

Also, change that "Hole is" - Portueta Japan - OK "6" is orect ME will fix

67727-3 rejested charges were made that charged Est us trans 30 points 10 + Made in the "Product of Japan Or

67727-4 He result channe not a real short of the Also Brance from EA + D Cot or - OK and

57

#### EPA Reg. No. 67727-2

- 1. In the ocular exposure section of the "First Aid" text, add "eye" as the last word of the second sentence (PR Notice 2001-1, section V.).
- 2. The semicolon following "Manufactured For," on the front label panel, should be replaced with a colon.
- 3. We note that the EPA Est. Number on the proposed label (06572-ID-001) differs from that presented on the last stamped, accepted label of July 2, 1999 (68738-JPN-001). An Idaho producer is now indicated. However, the next line of the proposed label reads, "Made in Japan." Also, the associated, revised CSF of March 8, 2001, still identifies a Est or But ask.

  Japanese producer for the product. This EPA Establishment inconsistency must be explained, and resolved by revising the label and/or CSF, as appropriate. See 40 CFR § the same previous that the proposed label reads, and resolved by revising the label and/or CSF, as appropriate. See 40 CFR § the same previous that the proposed label reads, and resolved by revising the label and/or CSF, as appropriate.

#### EPA Reg. No. 67727-3

- It is preferred that "Inert Ingredients" be changed to "Other Ingredients," in accordance with PR Notice 97-6.
- 2. In the ocular exposure section of the "First Aid" text, add "eye" as the last word of the second sentence (PR Notice 2001-1, section V.).

#### EPA Reg. No. 67727-4

 Because this is a registered product, "EPA Reg. Number 67727-4" must replace "EPA Reg. Number 67727-\*" throughout the proposed label. To expedite the review of revised labels, you may submit the individual corrected pages (rather than the entire labels) by fax ((703) 305-0118) to Denise Greenway, of my staff. Although the required CSF revisions are also minor, due to the proprietary nature of CSFs, replacement documents must not be faxed. To expedite the review of the revised CSFs, you are invited to hand deliver them, or arrange for courier delivery directly to Ms. Greenway. Should you have questions or concerns regarding this letter, please contact me, or telephone Ms. Greenway, on (703) 308-8263.

Sincerely,

Sheryl K. Reilly, Ph.D

Chief

Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511C)

Enclosure

DGreenway/308-8263/10-18-01/67727newmanprocetc.wpd/1,4-DMN

#### United States Environmental Protection Agency

OCT 2 5 2001

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D276 136	12
0276142	13
0276 144	13
and the second	ATT THE TENE OF

Margery M. Exton 3719 Thomasson Crossing Drive Triangle, Virginia 22172

Dear Ms. Exton:

Subject:

1,4Sight®

EPA Reg. No. 67727-1 1,4Sight® Technical EPA Reg. No. 67727-2

1,4SeedTM

EPA Reg. No. 67727-3

1,4Ship™

EPA Reg. No. 67727-4

Your Correspondence of March 28, 2001

On the behalf of your client, D-I-1-4, Inc., you submitted on March 28, 2001, a new manufacturing process and associated five-batch analysis. The two studies were assigned MRID numbers 453771-01 and 453771-02, respectively. Because the new manufacturing process yields active ingredient of higher purity than achieved via the method of record, your submission also included for each of the subject products a Confidential Statement of Formula (CSF) and label, amended to reflect the increased active ingredient concentration. The proposed labels were also otherwise revised.

The studies, CSFs and labels have been reviewed by the Biopesticides and Pollution Prevention Division, and our conclusions are stated below. The chemistry review (F. Toghrol to D. Greenway, September 13, 2001) is attached for your reference and convenience.

			CONC	URRENCES
SYMBOL .	7511C	75116	75MC	
SURNAME	Greenway	Toghrol	Rull	60
DATE -	10/19/01	10/23/01	16/25 80	
EPA Form 1320-	-1 (12-70)	***	11/01	OFFICIAL FILE COPY

#### MRID 453771-01

This study details changes in the last step of the manufacturing process, which result in increasing the 1,4-dimethylnaphthalene concentration from 94.7% to 98.4%. The study is acceptable.

#### MRID 453771-02

This study documents a preliminary analysis of samples produced using the revised method described above. The five-batch analysis is **acceptable**.

#### Confidential Statements of Formula

The March 8, 2001, CSF for the technical product (EPA Reg. No. 67727-2) is acceptable.

The March 8, 2001, CSFs for the three end-use products (EPA Reg. Nos. 67727-1, 67727-3 and 67727-4) are not acceptable. Each must be revised to parenthetically present the nominal concentration of the active ingredient in column 13(b), 14(a) and 14(b).

We have no objection to the documented addition of a 40 CFR § 180.1001(c) "cleared" fragrance to the formulation of EPA Reg. No. 67727-1.

#### Proposed Labels

The labels referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are not acceptable for the reasons given below.

### EPA Reg. No. 67727-1

- 1. It is preferred that "Inert Ingredients" be changed to "Other Ingredients," in accordance with Pesticide Registration (PR) Notice 97-6.
- 2. In the ocular exposure section of the "First Aid" text, add "eye" as the last word of the second sentence (PR Notice 2001-1, section V.).

# FIFRA

# CONFIDENTIAL BUSINESS INFORMATION DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (EO 12356)

Some information in the attached material may be entitled to treatment as trade secret or proprietary data section 7(d) and section 10 the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended.

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure while in his/her possession. Section 12(a)(2)(D) makes it unlawful for any employee to use to his/her own advantage or to reveal any confidential information (except to persons needing the information for the performance of official duties). A penalty of up to \$10,000 fine and up 3 years imprisonment may result from conviction of a violation on section 12(a)(2)(D).

Section 10(f) makes it a crime for any employee to disclose confidential information except as authorized by section 7 and 10 of FIFRA. A penalty of up to \$10,000 fine and up to one year in jail may result from conviction of a violation of section 10(f).

The attached information is not to be published, reproduced, publicly discussed, included in response to an FOI request or otherwise released without the explicit written authorization of the appropriate division or his designee.

Note that the attachment to the 10125/01 JAndersen to M Exton letter consisted only of the 2-page 9/13/01 premo from F Toghrol to D Greenway The DERs from the review were NOT forwarded to the 151 trant. DGreenway



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 1 3 2001

#### **MEMORANDUM**

SUBJECT: Registration Amendment of 1,4 Sight (EPA Reg. No.067727-1), 1,4 Sight

Technical (EPA Reg. No.067727-2), 1,4 Seed (EPA Reg. No.067727-3), and (1,4 Ship (EPA Reg. No.067727-4) Containing 97.4%, 98.,4%, 98.4%, and 63.8% 1,4-Dimethynaphthalene (respectively) as the Active Ingredient (Chemical No. 055802). Review of Amended Manufacturing Process for the Active Ingredient and Preliminary Analysis MRID No. 453771-01 and -02; Case No. 040626, 063181, 064425, and 065044; Submission No.: S596708, S596709; S596710, and

S5967-11; DP Barcode: D276132,, D276136, D276142, and D276144

FROM:

Freshteh Toghrol, Ph.D., Senior Scientist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division

TO:

Denise Greenway, Regulatory Action Leader

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division

#### **ACTION R REQUESTED**

D-1-1-4, Inc., requests (letter dated 3/28/01) an amended registration of 4 of the registered products 1,4 Sight (EPA Reg. No.067727-1), 1,4 Sight Technical (EPA Reg. No.067727-2), 1,4 Seed (EPA Reg. No.067727-3), and (1,4 Ship (EPA Reg. No.067727-4) containing 97.4%, 98.4%, 98.4%, and 63.8% 1,4-Dimethynaphthalene (1,4-DMN) as the active ingredient.

To support the amendment of these four products containing 1,4-DMN, the registrant has submitted an amended manufacturing process for the active ingredient (MRID No. 453771-01) and preliminary analysis of samples of new manufactured active ingredient (MRID No. 453771-

ROUTING AND TRANSMITTAL SLIP						
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1. Freshteh Tool	nrol please ana	ir d	I.T	10/23/9		
2. Linda Hollis	please cons	or	iH	10/28/01		
3. Sheryl Reilly	please sig	THE ST	an	10/25		
4.	0		OI.			
5 D. Greenway	tamp, issue, file, e	-				
Action	File		and Retu	m		
Approval	For Clearance		onversati			
As Requested	For Correction	Prepa	re Reply			
Circulate	For Your Information	See M	le			
Comment	Investigate	Signal	ture			
Coordination	Justify					
Amended poher	re: Non-fast track  Amended pohem data, CGFs tlabels for  Four 1,4-DMN products					
The attached letter alerts the consultant that the data are acceptable, but that CSF r label de ficiencies exist and most be resolved.						
Thanks						
Note: Jackets are not routed as another borrower is using some of DO NOT use this form as a RECORD of approvals, concurrences, disposals, them.						
cl	earances, and similar action	s b	000#	169		
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☆ U.S. G.P.O. 1991 281-781/	40010 Prescr	ibed by GSA (41 CFR) 1	01-11.20			

Incorrect cement

See replacement

page 8 1111/02

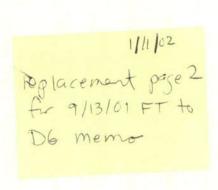
02).

#### Conclusions and Recommendations:

- 1. The amended manufacturing process in the last step of purification, which resulted in a higher percent purity of 1,4-Dimethynaphthalene (from 94.7% to 98.4%) is acceptable.
- 2. The preliminary analysis of five batches are acceptable. The results of five batches analysis of 1,4-Dimethynaphthalene showed purity of 99.3%, 98.8%, 98.5%, 98.6%, and 98.5%.
- 3. The revised CSF (dated 3/8/01) and the label for 1,4 Sight Technical (EPA Reg. No.067727-2) are acceptable.
- 4. The submitted revised CSF and the label for 1,4 Sight (EPA Reg. No.067727-1) are not acceptable. The registrant must submit a revised CSF and a revised label for 1,4 Sight (EPA Reg. No.067727-1). The revised label should remove the word "inert" ingredient and replace it with "other" ingredient. The revised CSF should indicate the nominal concentration of the active ingredient under column 13 (b), 14(a), and 14(b).
- 5. The submitted revised label and CSF for 1,4 Seed (EPA Reg. No.067727-3) are not acceptable. The registrant must submit a revised CSF and a revised label for 1,4 Seed (EPA Reg. No.067727-3). The revised label should remove the word "inert" ingredient and replace it with "other" ingredient. The revised CSF should indicate the nominal concentration of the active ingredient under column 13 (b), 14(a), and 14(b).
- 6. The submitted revised label is acceptable for 1,4 Ship (EPA Reg. No.067727-4), but the revised CSF for 1,4 Ship (EPA Reg. No.067727-4) is not acceptable. The registrant must submit a revised CSF for 1,4 Ship (EPA Reg. No.067727-4). The revised CSF should indicate the nominal concentration of the active ingredient under column 13 (b), 14(a), and 14(b).

#### Conclusions and Recommendations:

- 1. The amended manufacturing process in the last step of purification, which resulted in a higher percent purity of 1,4-Dimethynaphthalene (from 94.7% to 98.4%) is acceptable.
- 2. The preliminary analysis of five batches are acceptable. The results of five batches analysis of 1,4-Dimethynaphthalene showed purity of 99.06%, 98.39%, 98.12%, 98.37%, and 98.14%.
- 3. The revised CSF (dated 3/8/01)and the label for 1,4 Sight Technical (EPA Reg. No.067727-2) are acceptable.
- 4. The submitted revised CSF and the label for 1,4 Sight (EPA Reg. No.067727-1) are not acceptable. The registrant must submit a revised CSF and a revised label for 1,4 Sight (EPA Reg. No.067727-1). The revised label should remove the word "inert" ingredient and replace it with "other" ingredient. The revised CSF should indicate the nominal concentration of the active ingredient under column 13 (b), 14(a), and 14(b).
- 5. The submitted revised label and CSF for 1,4 Seed (EPA Reg. No.067727-3) are not acceptable. The registrant must submit a revised CSF and a revised label for 1,4 Seed (EPA Reg. No.067727-3). The revised label should remove the word "inert" ingredient and replace it with "other" ingredient. The revised CSF should indicate the nominal concentration of the active ingredient under column 13 (b), 14(a), and 14(b).
- 6. The submitted revised label is acceptable for 1,4 Ship (EPA Reg. No.067727-4), but the revised CSF for 1,4 Ship (EPA Reg. No.067727-4) is not acceptable. The registrant must submit a revised CSF for 1,4 Ship (EPA Reg. No.067727-4). The revised CSF should indicate the nominal concentration of the active ingredient under column 13 (b), 14(a), and 14(b).



# FIFRA

# CONFIDENTIAL BUSINESS INFORMATION DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (EO 12356)

Some information in the attached material may be entitled to treatment as trade secret or proprietary data section 7(d) and section 10 the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended.

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure while in his/her possession. Section 12(a)(2)(D) makes it unlawful for any employee to use to his/her own advantage or to reveal any confidential information (except to persons needing the information for the performance of official duties). A penalty of up to \$10,000 fine and up 3 years imprisonment may result from conviction of a violation on section 12(a)(2)(D).

Section 10(f) makes it a crime for any employee to disclose confidential information except as authorized by section 7 and 10 of FIFRA. A penalty of up to \$10,000 fine and up to one year in jail may result from conviction of a violation of section 10(f).

The attached information is not to be published, reproduced, publicly discussed, included in response to an FOI request or otherwise released without the explicit written authorization of the appropriate division or his designee.

# 1,4SIGHT® TECHNICAL

Aerosol Grade - Plant Growth Regulator

			By Weight,
Active Ingredient:	1,4-Dimethylnaphthalene*		. 98.4%:
TOTAL		.,,	100.0%
* Contains 8.3 pounds	active ingredient per gallon.	Se Die Ri	

## Keep Out of Reach of Children WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. ᢓ╡ᢓ ←     Call a poison control center or doctor for treatment advice.
<ul> <li>Call a poison control center or doctor immediately for treatment advice</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

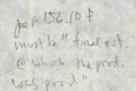
#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### See Directions for Use on Reverse Net Contents

Manufactured For; D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA



EPA Reg. Number 67727-2

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#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

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This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

#### PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

#### PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

#### CONTAINER DISPOSAL

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

#### CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



## Master Label 1,4SEED<sup>™</sup>

#### Aerosol Grade - Seed Potato Dormancy Enhancer

**Product Benefits:** 

Naturally occurring plant biochemical delays sprouting, resulting in more vigorous seed growth; [and/or]

Enhances the potato's ability to heal cuts and bruises; [and/or]

Reduces respiration, resulting in less water loss; [and/or]

Reduces Refrigeration and ventilation needs; [and/or]

Reduces pressure bruising; [and/or]
Firmer potatoes with improved visual appearance.

		By Weight
Active Ingredient:	1,4-Dimethylnaphthalene*	98.4%
Inert Ingredients:		1.6%
TOTAL		100.0%

\* Contains 8.3 pounds active ingredient per gallon.

other

# Keep Out of Reach of Children WARNING

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
lf on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**Emergency Information** 

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

Net	Contents	

Manufactured For: D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680 USA EPA Reg. Number 67727-3 EPA Est. Number 68738-JPN-001 Made in Japan Revision 1

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

# PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

# PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

# CONTAINER DISPOSAL

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

# **Continue Directions for Use on Reverse**

# NOTICE

- 1.4SEED<sup>™</sup> is used as an aerosol to enhance the dormancy of seed potatoes prior to germination.
- Applicators and other handlers must wear: long-sleeved shirt, long pants, shoes, socks, protective eyewear (goggles or face shield), and chemical resistant (such as nitrile or butyl) gloves.
- For reentry into treated areas during application and prior to ventilation or settling of aerosol fog, workers must
  wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or
  butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic
  vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH
  approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.
- 1,4SEED must not be applied to potatoes in the field.
- 1,4SEED may be applied anytime after the potatoes are placed into the storage area.
- Do not allow vapors to come in contact with storage areas used for seed potatoes within 60 days of their planting.

# FORCED AIR DISTRIBUTION METHOD

- 1. Prepare aerosol generating equipment. The discharge from the vaporizer should be located to provide optimum distribution in the storage area. Take precautions to prevent the spray from coming into direct contact with the potatoes.
- 2. Running fans during the application may aid disbursement of vapors, but is not required.
- 3. It is advantageous to keep the storage area closed as long as practical to allow for maximum absorption into the potatoes.

# TREATMENT OF STORAGE AREAS THAT DO NOT HAVE RECIRCULATING AIR SYSTEMS

These storage areas are more difficult to treat. Additional steps must be taken to treat these storage areas.

- 1. Prepare aerosol generating equipment. The discharge from the vaporizer should be located to provide optimum distribution in the storage area. Take precautions to prevent the spray from coming into direct contact with the potatoes.
- 2. Completely close off the area to be treated. This may include vent doors in the attic and walk doors around the perimeter. The large truck doors may need to be sealed to prevent excess leakage.
- 3. Begin treatment by following the listed steps;
  - A. Start the aerosol generator.
  - B. Adjust the location of the vaporizer so all the storage area receives an equal amount of aerosol fog. It may be necessary to move the vaporizer during the application or make the application in multiple phases. For

reentry into treated areas during application and prior to ventilation or settling of the aerosol fog, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.

4. Wait at least 12 hours before fresh air is introduced into the storage area, then return the storage area to "normal" operation.

5. It is advantageous to keep the storage area closed as long as practical to allow for maximum absorption into the potatoes.

# APPLICATION TIMING AND RATES

Application of 1,4SEED <sup>™</sup> can be made anytime after the potatoes are placed in the storage area.

1. Apply at rates of up to 1 pound of active ingredient per 50,000 lbs (500 cwt), which is equivalent to 20 ppm on a product to potato basis or 1 gallon per 4,000 cwt.

While potatoes may be retreated as necessary for effective control, do not exceed the maximum application of 80 ppm during the storage season.

1 cwt. = 100 lbs = 2.5 cubic feet; 1 ton = 20 cwt.

# CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

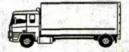




# Labeling To Be On Outer Box 1,4SHIP™

Ready-To-Use Aerosol Potato Dormancy Enhancer





# For Use on Potatoes Prepared for Transportation

		By weigh	I
Active ingredient:	1,4-Dimethylnaphthalene*	63.8%	
		36.2%	
		100%	17.80

\* Contains 3.83 ounces active ingredient per can.

check

# Keep Out of Reach of Children WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. May be harmful if inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Avoid breathing spray mist or vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

# First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in <u>Eyes</u>: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If <u>Swallowed</u>: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on <u>Skin or Clothing</u>: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

<u>If Inhaled</u>: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

**Emergency Information** 

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

# **Physical or Chemical Hazards**

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the "Directions for Use" on this label very carefully.



Where is ry No.

# HIGHLY FLAMMABLE INGREDIENT INGREDIENTE ALTAMENTE INFLAMABLE

Do Not Smoke During Application or Near Treated Area!
Net Contents 6 ounces

Manufactured For: D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680-0860 USA EPA Reg. Number 6 77:27-4 277-27-4
EPA Est. Number 11623-GA-1 OK
Revision 1

# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

# PESTICIDE STORAGE

 Store product in unopened, labeled packaging. Do not store product near or expose product to sources of heat, including open flame, sparks, welding operations, etc.

# PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

# CONTAINER DISPOSAL

Do not puncture or incinerate. Discard container in trash.

# NOTICE

- 1,4SHIP<sup>™</sup> is a ready-to-use aerosol which enhances the dormancy of potatoes prepared for transportation.
- During and for 30 minutes after the application, do not smoke, weld, cut metal, or allow open flame, high temperature surfaces, or other ignition sources to be near the treated area.
- Applicators and other handlers must wear: long-sleeved shirt, long pants, shoes, socks, protective eyewear
   (goggles or face shield), and chemical resistant (such as nitrile or butyl) gloves.
- When either a rail car or cold storage room is treated with more than one can, applicators and other handlers
  must additionally wear a respirator. Refer to the reentry statement below for acceptable respirator type.
- For reentry into treated areas during application or within 30 minutes post-application, for emergencies only, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.
- 1,4SHIP<sup>™</sup> is a short term dormancy enhancer which will not adversely affect eventual germination of seed potatoes.
- Let 60 days elapse before using a treated area as storage of seed potatoes. Air system and building must be thoroughly ventilated before area is used for storage of seed potatoes.
- Do not allow vapors to come in contact with storage areas used for seed potatoes within 60 days of their planting.

# APPLICATION OF 1,4SHIP™

(Can graphic to be inserted here - See attached image.)

- Fill the area to be treated (truck, rail car, shipping container, or cold storage room) with potatoes and close all but the exit door.
- 2. Turn off all electrical equipment (air circulators, refrigeration, etc.) in the treatment area prior to application. Turn off lighting in treatment area, and allow to cool prior to application.
- 3. Remove top portion of box by pulling the separator at the arrow symbol. Take out the enclosed 1,4SHIP™ tag and note the date and time of application on the space provided.
- Position the box(es) containing the can(s) in opposite corners of the treatment area, so vapors will be
  dispersed throughout the area. In trucks, place box(es) at the end farthest away from the refrigeration unit
  (near doors).
- 5. Remove the back side of the double-sided tape and adhere the box containing the can to an inside cargo wall, in an area with some open volume of air around it.
- 6. Without removing the can from the box, remove the can cap and depress the trigger until it locks.
- 7. Immediately leave the area and close the exit door.
- 8. Feed a door seal through the 1,4SHIP™ tag and affix the seal to the exit door.
- 9. Do not open or enter treated area for at least 30 minutes. Do not start any electrical system within the cargo

area for at least 30 minutes.

10. It is advantageous to keep the treated area closed as long as practical to allow for maximum product absorption into the potatoes.

# APPLICATION TIMING AND RATE

Application of 1,4SHIP™ can be made anytime after the potatoes are removed from storage, prepared for shipment, and placed either in a truck, sea-going shipping container, rail car, or a cold storage room. Do not exceed recommended maximum number of cans. At the maximum use rate, this can will treat 20,000 lbs (200 cwt) of potatoes.

- 1. In trucks and shipping containers, apply at the rate of up to 2 cans per 40,000 lbs (400 cwt) of potatoes.
- 2. In rail cars, apply at the rate of up to 6 cans per 120,000 lbs (1200 cwt) of potatoes.
- In cold storage rooms, apply at a maximum rate of 1 can per 1500 cubic feet and 20,000 lbs (200 cwt) of potatoes.

1 cwt. = 100 lbs = 2.5 cubic feet; 1 ton = 20 cwt.

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# **CONDITIONS OF SALE**

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

# Labeling To Be On Can 1,4SHIP™

		О	vveignt .
Active ingredient: 1	,4-Dimethylnaphthalene*	 	63.8%
Other ingredients:			36.2%

EPA Reg. Number 67727-\*

Follow the Directions for Use as labeled on the outer carton when applying this product.

# Keep Out of Reach of Children WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. May be harmful if inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Avoid breathing spray mist or vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

# First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

**Emergency Information** 

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

# **Physical or Chemical Hazards**

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the "Directions for Use" on this label very carefully.



# HIGHLY FLAMMABLE INGREDIENT INGREDIENTE ALTAMENTE INFLAMABLE

Labeling To Be On 1,4SHIP<sup>™</sup> Tag
(will be enclosed in box, and
hole-punched with a reinforced grommet)

1,4SHIP<sup>™</sup> Application
Do Not Open Or Enter
Until 30 Minutes From
Date
Time

# Can Graphic for Use on 1,4SHIP Label



# REQUEST FOR WORK TO BE DONE BY THE CONTRACTOR

Date: July 31, 2001

(2) Name of Contractor: Tetrahedron Inc.

(3) Task No: 2-005 - Amendment 2

(4) EPA Requesting Branch Chief: Sheryl Reilly/BPB Tele.#: (703) 308-8269
EPA Secondary Reviewer: Freshteh Toghrol/BPB Tele.#: (703) 308-7014 F. T.

(5) Chemical Name: Naphthalene, 1,4-dimethyl

(6) CBI: YES X NO FIFRA: YES X NO \_

(7) <u>Description for Each Study</u>: --- Identify the type of study to be evaluated, provide the information requested and describe the type of work to be performed if different from the following statement - be specific.

C. 067727-2 Chem: Naphthalene, 1,4-dimethyl; Date required by: August 24, 2001

DP barcode: D276136; Submission: S596709

Registration: N/A Reregistration: N/A Special Review: N/A

Evaluate and prepare a DER for the following studies:

STUDY description	MRID#	# Hrs	DER
Manufacturing Process for 1,4- Dimethylnaphthalene	453771-01	4	yes
Five Batch Analysis	453771-02	4	yes
Total Number of Review Hours Assigned		8	

Appl	oval: George Ghali		
	Work Assignment Manager	Date	
	Caroline Gordon		
	Project Officer	Date	

DE: D276136

ISSION: S596709

CASE: 063181 DATA PACKAGE RECORD

BEAN SHEET

DATE: 07/11/01 Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 345 TECH-FORMULA CHANGE AMND

CHEMICALS: 055802 Naphthalene, 1,4-dimethyl- (8CI,9CI)

94.7000%

ID#: 067727-00002 1,4-SIGHT TECHNICAL

COMPANY: 067727 D-I-1-4 INC

PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL DENISE GREENWAY 703-308-8263 ROOM: CS1 PM TEAM REVIEWER: 5TH FL

RECEIVED DATE: 04/02/01 DUE OUT DATE: 07/01/01

\* \* \* DATA PACKAGE INFORMATION \* \* \*

BARCODE: 276136 EXPEDITE: N DATE SENT: 07/11/01 DATE RET.: / /

CHEMICAL: 055802 Naphthalene, 1,4-dimethyl- (8CI,9CI)

DP TYPE: 001

CSF: Y LABEL: Y ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 08/25/01 DIV : BPPD NEGOT DATE: / / / BRAN: BPPD-IO PROJ DATE: SECT: IO REVR : CONTR:

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Attached for your review are a new manufacturing process (MRID 453771-01), a new 5-batch analysis (MRID 453771-02), a revised label, and a revised CSF (dated 3/8/01). Also included are a copy of the 3/28/01 incoming correspondence, and a copy of the previous manufacturing process (MRID 430825-02), for your convenience. Please determine the acceptability of the two studies and indicate if the information presented in them is correctly represented in the label and CSF. FYI, the data have been relied upon by the registrant to similarly update the labels/CSFs of their other products (67727-1, -3 and -4), for which separate "bean sheets" have been prepared.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

LABEL DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF

BPPI	) PRAT	TOT. TOU	A CODT	ING O	Rin	
Margery M. PM 90: Janet Ande			A PENERL	The lands	5/8/01 e Greme	
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EPA REG./FILE SYN	VIBOL 67	727-1,2,3,	4	Λ		
ACTION CODE_3				Amendon	enT	
(NEW a.i./EUPs/Tol	erances: Yes	/No	)			
SUBMISSION BARC	ODE <u>S 596</u>	709, 5596708	5596710	5 5 96711		
DATE ON APPLICA	TION_3/	28/01				
EPA RECEIVED DA						
PM RECEIVED DAT	re 4 19	101				
ASSIGNED IN PRAT						
COMPLETED BY:_	6 Bethe	EG BADATE:	5/4/0	. 1		801
			Napht	halone, 1,4 ecceptoses	- DIME+HYL-S	(801, 901) 99
FINAL ACTI	ON				*	
Response Code 12						
Response Date: 013	25/01-					
MOS:	(1) Cite-All					
	(4) Not Appli	icable				
	(8) Selective					
CRP:	Y es	No				
Restricted Use:	Yes	No				
Manufacturing Use:	Yes	N)				84
Exclusive Use:	120	N =				04

Form Approved. OMB No

70-0060. Approval expires 2-28-9



United States

# **Environmental Protection Agency**

Washington, DC 20460

	Registration
~	Amendment
	Other

**OPP Identifier Number** 

284700

	Α	pplication	for Pestic	ide - Sec	ction I			
1. Company/Product Number 67727-2				Product Mar eenway	nager	3. P	Proposed Classi	Restricted
4. Company/Product (Name) D-I-1-4, Inc./ 1,4Sight 7	Technical		PM# 90°	91				
5. Name and Address of App D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680-0		e)	(b)(i), to: EPA	my product	veiw. In accorda is similar or iden	tical in c	omposition ar	nd labeling
			Section -					
Amendment - Explain Resubmission in responsible in Notification - Explain  Explanation: Use addition Change in basic formulation, CSF and revised labeling. Somodified in compliance with Page 1985.	below.  al page(s) if necessary.  reducing the number and ee two supporting studies	(For section I	and Section II.	Final printe Agency let "Me Too"  Other - Exp	Application.  plain below.  active ingredient pu	rity level is	s reflected on th ments are also b	e enclosed being
		-	Section -	III				
1. Material This Product Will	Be Packaged In:							
Child-Resistant Packaging Yes No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	Water Soluble Yes No If "Yes" Package wgt	No. per containe	2. Type of	Metal Plastic Glass Paper	r Specify)	
3. Location of Net Contents I	nformation 4	. Size(s) Retail	Container		5. Location of Lat	pel Directi	ons .	
6. Manner in Which Label is a	Affixed to Product	Lithograp Paper glo Stenciled	beu	Othe	or			_
			Section -	V				
1. Contact Point (Complete)	tems directly below for	identification (	of individual to	e contacted,	if necessary, to pr	ocess this	s application.)	
Name Margery M. Exton		10.0	tle gent of Record			Telephor (703) 22	ne No. (Include 1-6639	Area Code)
	nents I have made on the knowlingly false or minaw.	3.	l attachments ti				6. Data Appli Received (Stam	•••••
Margery M. Extor			3-8-	01				85

<b>≎EPA</b>	Environmental	Protection pton, DC 2046	Enthalter and the second		Registra Amenda Other		OPP Identifier Number
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4. Company/Product (No	ame)	ight in a	PM#	articles of a second	a 13 year Soles) arrigin and less	Full E	None Restricte
	Applicant (Include ZIP Code  f this is a new address		(b)(i), to: EPA				FIFRA Section 3(c)(3) emposition and labeling
eason included the six	The major the time and a second	alter to 10,6	Section -	He was been	/	constant	and professional property
Notification - Exp	response to Agency letter delain below.		/	Agency letter of "Me Too" App	lication.	den den de	
a standard	and the second	SP-TA-E	Section -	III - A	de des		a new span
1. Material This Product	Will Be Packaged In:	/		The second second	Carlotte 55	100	Stratome, fair
Child-Resistant Packagin	Yes No	No. per container	Water Soluble  Ves  No  If "Yes"  Package wgt	No. per	2. Type of	Metal Plastic Glass Paper	Specify)
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3. Location of Net Cont	Container	The second second second	il Container	The second of	On Labe	De Tr	ons mpanying product
6. Manner in Which Lab	el is Affixed to Product	Lithogra Paper gl Stencile	ph lued d	Other _	organia and design	Marie III	breen sum to
NAC STATE		C. HART TO T	Section -	IV \		the "the	The second second
1. Contact Point [Comp	plete tems directly below for	CHARLES THE PARTY OF	OFFICE OF THE STATE OF	be contacted, if n	ecessary, to pi	THE PERSON NAMED IN	THE PERSON NAMED IN COLUMN
Name		T	Title			Telephor	ne No. (Include Area Code)
	state <mark>m</mark> ents I have made on t at any knowingly false or mi able law.		ion Ill attachments t	hereto are true,\a			6. Date Application Received (Stamped)
2. Signature		3.	. Title	and the second	Mary and		231

5. Date

4. Typed Name

# PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
  basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

<u>SECTION II</u> - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a <u>specific EPA-registered product</u>. This section is <u>not</u> to <u>be</u> used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

<u>SECTION III</u> (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
- Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

Please read instruction	s on reverse before completing form
<b>≎EPA</b>	United States Environmental Protection A Washington, DC 20460

Registration

OPP Identifier Number

Environmental Protect Washington, DC 20	100000000000000000000000000000000000000
Applicat	ion for Pesticide - Section I
1. Company/Product Number	2. EPA Product Manager 3. Proposed Classification
4. Company/Product (Name)	PM# 9 None Restricted
5. Name and Address of Applicant (Include ZIP Code)  Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name
1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Section - II
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Application.  Other - Explain below.
Explanation: Use additional page(s) if necessary. (For section	Section - III
	Section - III
1. Material This Product Will Be Packaged In:  Child-Resistant Packaging  Yes  No  * Certification must be submitted  No. per Container	Water Soluble Packaging  Yes  No  If "Yes" Package wgt  No. per container  Other (Specify)
3. Location of Net Contents Information 4. Size(s) R  Label Container	5. Location of Label Directions On Label On Labeling accompanying product
6. Manner in Which Label is Affixed to Product  Litho Pape Sten	ograph er glued noiled Other
10	Section - IV
1. Contact Point   (Complete items directly below for identification)	tion of individual to be contacted, if necessary, to process this application.)
Name	Title Telephone No. (Include Area Code)
Certific I certify that the statements I have made on this form as I acknowledge that any knowingly false or misleading st both under applicable law.	nd all attachments thereto are true, accurate and complete.
2. Signature	3. Title
4. Typed Name	5. Date

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Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

D-I-1-4, INC. P.O. BOX 860 MERIDIAN, ID 83680

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/02/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# TRANSMITTAL DOCUMENT FOR DATA SUBMITTED IN SUPPORT OF 1,4Sight Technical EPA FILE SYMBOL 67727-2

1. Name and Address of Submitter:

D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83680

2. Regulatory Action in Support of Which This Package is Submitted:

Change in Formulation

- 3. Transmittal Date: March 8, 2001
- 4. <u>List of Submitted Studies:</u>

MRID NUMBER 45377101

Document 1 Manufacturing Process for 1,4-

Dimethylnaphthalene. Data Requirement: 830.620. Margery M. Exton. March 5,

2001. 4 pages.

45377102

Document 2 An

Analysis of Samples - Five Batches of 1,4-Dimethylnaphthalene. Data Requirement: 830.1700. Erik Quissell. Balivi Research Laboratories, 2307 E. Commercial Street, Meridian, ID 83642. July 10, 2000. 54

pages.

iccie

Ms. Denise Greenway March 28, 2001 Page 2

Please feel free to contact me on (703) 221-6639 if you have any questions about these submissions, and would like to discuss them further. As always, we look forward to working with you as we continue to develop D-I-1-4's product line.

Sincerely,

Margery M/Exton

Pesticide Regulatory Consultant

enclosures

. . . . .

Correct

# Margery M. Exton



# Consultant Pesticide Regulatory Affairs

March 28, 2001

Attn: Denise Greenway
PM Team 90
Biopesticides and Pollution Prevention Division (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: D-I-1-4, Inc. Submissions on 1,4-DMN Products EPA Registration Numbers 67727-1, -2, -3, and -4

Dear Ms. Greenway:

Enclosed please find four submissions for amendment of D-I-1-4's products containing 1,4-Dimethylnaphthalene (1,4-DMN). As we have discussed in person at some time past, the manufacturer of 1,4-DMN has devised a new manufacturing method which enables them to produce 1,4-DMN with fewer impurities. D-I-1-4 is therefore submitting amendments for each of their 1,4-DMN-based products, in order to reflect an increased purity level of the active ingredient.

Per the Agency's guidance, a revised description of the manufacturing process, along with a new five-batch analysis, is being submitted in support of these amendments. These data show that the technical grade product can be produced at a purity of 98.4%. Consequently, the purity levels of the end-use products will rise as well.

The registrant is also using this opportunity to make several other minor changes to the products. First aid statements are being brought into compliance with PR Notice 2001-1. The word "hormone," as used on two of the label's product benefits section, was inaccurate. D-I-1-4 therefore requests replacing it with the word "biochemical." A formulation is requested for 1,4Sight which allows a small amount of fragrance to be added to the product. The fragrance of choice is approved for use as an inert ingredient in products applied to crops post-harvest.

	each of the attached submissions, please find: A completed application form;	•
	A revised CSF (two copies); and	
	Revised labeling (five copies);	
In ac	ldition, the submission for the technical product includes the following:	
-		
In ac	Idition, the submission for the <u>technical</u> product includes the following: Transmittal document (three copies); Final Report, Manufacturing Process (three copies); and	·:::

# 1,4-DMN Submissions Cheat Sheet

Denise -- here's a quick look at what we are trying to accomplish for each of the 1,4-DMN products.

# 1.4Sight Technical

1. Increase purity - reflected on CSF and label.

A.I. = 98.4%, Other = 1.6%

Contains 8.3 #s ai per gallon.

- 2. Modify first aid statements to comply with PR Notice 2001-1.
- 3. Remove the second appearance of the signal word, as all precautionary and first aid labeling are on the first panel.

1,4Sight

1. Increase purity - reflected on CSF and label.

A.I. = 97.4%, Other = 2.6%

Contains 8.2 #s ai per gallon

- 2. Add fragrance to the product.
- 3. Modify first aid statements to comply with PR Notice 2001-1.
- 4. Change the word "hormone" to "biochemical" in product benefits section.
- 5. Remove the second signal word.

# 1,4Seed

1. Increase purity - reflected on CSF and label.

A.I. = 98.4%, Other = 1.6%

Contains 8.3 #s ai per gallon.

- 2. Modify first aid statements to comply with PR Notice 2001-1.
- 3. Change the word "hormone" to "biochemical" in product benefits section.
- 4. Remove the second signal word.



# 1,4Ship

1. Increase purity - reflected on CSF and label.

A.I. = 63.8%, Other = 36.2%

Contains 3.83 #s ai per gallon.

Note: First Aid statements already comply with PR Notice 2001-1.



# 1,4SIGHT® TECHNICAL

Aerosol Grade - Plant Growth Regulator

By Weight
98.4%
1.6%
100.0%

Active Ingredient: 1,4-Dimethylnaphthalene
Other Ingredients:
TOTAL

\* Contains 8.3 pounds active ingredient per gallon.

# Keep Out of Reach of Children WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	First Aid  Have the product container or label with you when calling a poison control center or doctor, or going for treatment.		
<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>			
Call a poison control center or doctor immediately for treatme Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison contror doctor. Do not give anything by mouth to an unconscious person.			
lf on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>		
	Emergency Information		

# **Environmental Hazards**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See	<b>Directions</b>	for	Use	on	Reverse
	Net Con	ten	ts		

Manufactured For; D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA EPA Reg. Number 67727-2 EPA Est. Number 06572-ID-001 Made in Japan Revision 1

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its leveling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight® Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

# PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

# PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

# **CONTAINER DISPOSAL**

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

# **CONDITIONS OF SALE**

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

# FRONT END PROCESSING APPLICATION INFORMATION CHECK LIST PM\_\_\_9/\_ EPA COMPANT NUMBER 67727-2 EPA REGISTRATION NUMBER STATUS ACTIVE \_\_\_\_ CANCELLED\_\_\_\_ (FOR AMENDMENTS) NOT IN REFS\_\_\_\_\_ NOT IN REFS\_\_\_\_\_ NOT IN REFS\_\_\_\_\_

OPP# <u>784700</u> DATE <u>4-12-01</u>

1

**AMENDMENT** 

# APPLICATION FOR AMDENDMENT

WITH DA	<u>TA</u>	WITH	OUT DATA
INIT.	DATE	INIT.	DATA
FEU-LIW	4-12-01	FEU	
SIG. (DATA)		PM	
PM 9/			
	OPP # 28	4700	



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

04/12/2001

MARGERY M. EXTON MARGERY M. EXTON P.O. BOX 860 MERIDIAN ID 83680

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: 1,4SIGHT TECHNICAL

COMPANY NAME: D-I-1-4, INC.

OPP IDENTIFICATION NUMBER: 284700 EPA REGISTRATION NUMBER: 67727-2 EPA RECEIPT DATE: 04/02/2001

SUBJECT: RECEIPT OF AMENDMENT

# DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Sheryl Reilly, Product Manager 91, at (703) 308-8269.

Sincerely,

Front End Processing Staff Information Services Branch

Program Management and Support Division

Final Printed Label Review:

EPA Reg. No. 67727-2

**Submission Date:** 

**September 21, 1999** 

Pin Punch Date:

**September 23, 1999** 

Two versions of the Final Printed Label (FPL) were submitted: one for each EPA Establishment Number used by the registrant. See incoming letter for explanation. The only observed difference between the stamped accepted version, dated 7/2/99, and the FPL is the use of leading zeros in the EPA Establishment Number. The only other notable observation is the retention in the FPL of the line "Revision1" on page one.

**CONCLUSION:** 

The subject FPL was reviewed and found to be in compliance with the

stamped accepted label dated July 2, 1999.

Denise Greenway

Regulatory Action Leader

BPPD 9/28/99

S568899 300 - 37

# DLLN LUVI HOTTON PORTME LARW rcia. 9/27/99 REVIEWER: Denise Freenway FM 90: Janet Andersen · (ASSIGIZE 6Y: EPA REGIFILE SYMBOL 677.27-2 Final Printed labeling ACTION CODE 300 SUBMISSION BARCODE 55688 Date on Application EPA Received Date PM\_Received Date Assigned in PRAT YES NO Date 7/27 Completed by T. Bethea -FINAL ACTION Response Code 3 + Researce Date: 9/28/99. MOS: \_\_\_\_\_\_(1) Cite All \_\_\_\_(4) Not Applicable \_\_\_\_(8) Selective CRP:

Restricted Use:

Exclusive Use:

Manufacturing Use:

Yes

Yes .

A: FPL67727-2

no close PRATI

101

# Margery M. Exton

# Consultant Pesticide Regulatory Affairs

September 21, 1999

Denise L. Greenway
Biopesticides and Pollution Prevention Division 
Mailcode 7511W
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Final, Printed Labeling for EPA Registration 67727-2, Product 1,4Sight Technical

Response to Agency Letter dated July 2, 1999

Dear Ms. Greenway:

On behalf of my client, D-I-1-4, Inc., I am submitting two copies of final, printed labeling for 1,4Sight Technical, EPA Registration 67727-2. I have enclosed two copies of each version of the final labeling - the difference being the EPA establishment number. While the product is made in Japan, if D-I-1-4 re-packages the product in smaller containers, they will use the label bearing their Idaho establishment number.

Thank you for your assistance in registering this new product, and your continued guidance in D-I-1-4 projects.

Sincerely,

Margery Extern Margery M. Exton Agent of Record

D-I-1-4, Inc.

Enclosures

(1) Application Form

(2) Final, Printed Labeling (two copies of each version)

cc: John Forsythe, D-I-1-4 Inc. Darol Forsythe, D-I-1-4 Inc.

Form Approved. OMB No. 2070-0060, Approvel expires 2-28-95



**United States** 

# Environmental Protection Agency

	Registration
	Amendment
,	Oahaa

**OPP Identifier Number** 

Washington, DC 20		✓ Other	
Applicati	on for Pesticide - Sec	tion I	
1. Company/Product Number 67727-2	2. EPA Product Man Denise Greenway		roposed Classification
4. Company/Product (Name) D-I-1-4, Inc., 1,4Sight Technical	PM# 90		None
5. Name and Address of Applicant (Include ZIP Code) D-I-1-4 Inc. P.O. Box 860 Meridian, Idaho 83680	(b)(i), my product i to:	reiw. In accordance with is similar or identical in co	omposition and labeling
Check if this is a new address	Product Name		
	Section - II		
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Final printed Agency lett "Me Too" A	Application.	ly 2, 1999
Explanation: Use additional page(s) if necessary. (For section Final, Printed Labeling - two copies per Agency Letter	n I and Section II.)		
	Section - III		
Material This Product Will Be Packaged In:			
Child-Resistant Packaging  Yes  No  No  If "Yes" Unit Packaging  No. per Unit Packaging wgt.  No. per Container	Water Soluble Packaging  Yes  No  If "Yes"  Package wgt  No. per  Package wgt  No. per	2. Type of Container  Metal Plastic Glass Paper Other (S	Specify)
be submitted	rackage wgt contains	Other to	specify
3. Location of Net Contents Information 4. Size(s) Re Label Container	Itail Container	5. Location of Label Direction	ons
6. Manner in Which Label is Affixed to Product Paper Stend	graph Other glued iiled		
	Section - IV		
1. Contact Point (Complete items directly below for identification)	on of individual to be contacted, i	if necessary, to process this	application.)
Name Margery M. Exton	Title Agent of Record	Telephone (703) 221	e No. (Include Area Code)
Certification of the control of the	all attachments thereto are true	1	6. Date Application Received (Stamped)
2. Signature Margery Exton	3. Title Agent of Record		
4. Typed Name Margery M. Exton	9-21-99		103

# 1,4SIGHT® TECHNICAL

# Aerosol Grade - Plant Growth Regulator

		By vveight
Active Ingredient:	1,4-Dimethylnaphthalene*	94.7%
Other Ingredients:		5.3%
TOTAL		100.0%
* Contains 7.9 pounds	active ingredient per gallon.	

# Keep Out of Reach of Children

# WARNING

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

# WARNING

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

# Statement of Practical Treatment

If in Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If <u>Swallowed</u>: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.

If on the Skin: Wash with plenty of soap and water. Get medical attention.

# **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

# **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

# See Directions for Use on Reverse

Net (	Content	2
1405	JOHILLIA	

Manufactured For; D-I-1-4, Inc. P.O. Box 860. Meridian, ID 83680 USA EPA Reg. Number 67727-2

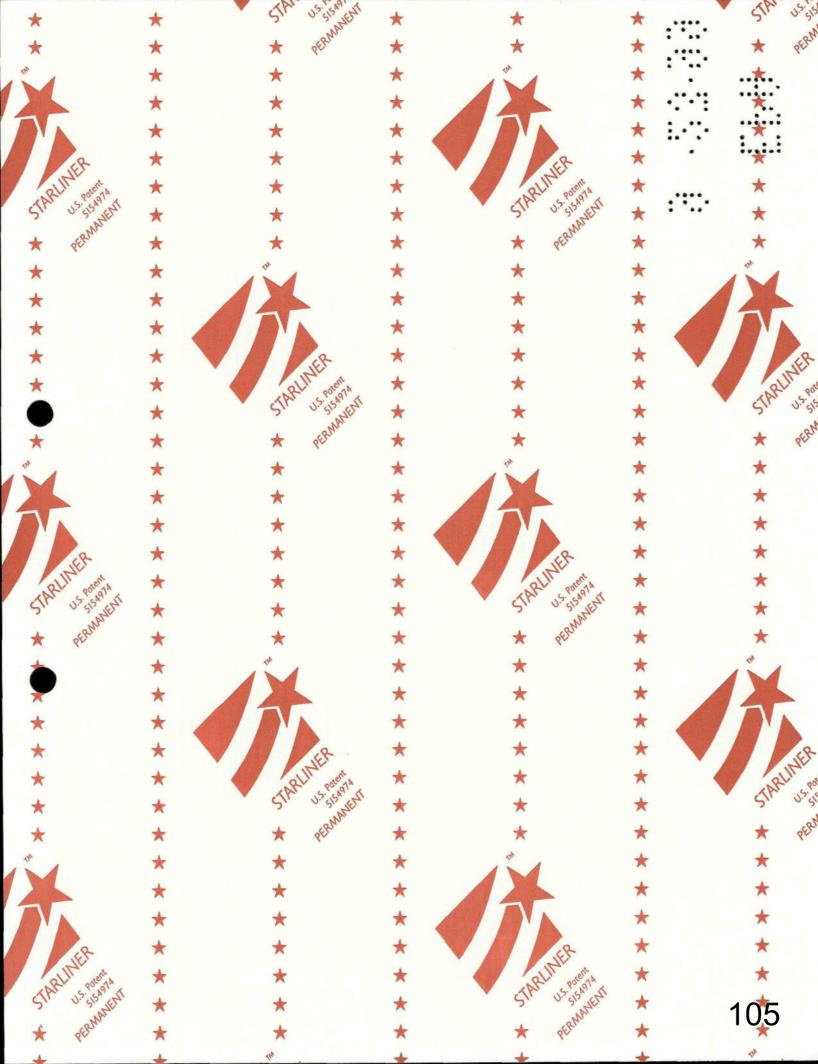
EPA Est. Number 065726-ID-001

Made in Japan

Revision 1



104



# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight® Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

# PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

# PESTICIDE DISPOSAL

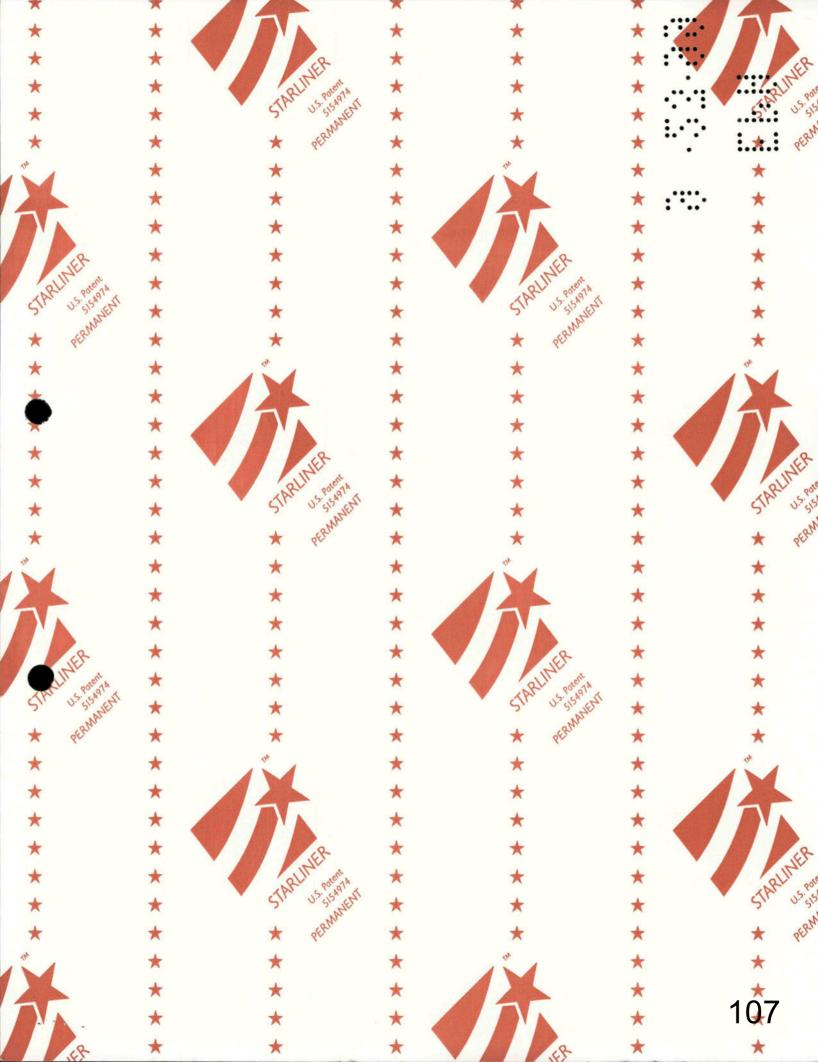
 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

# CONTAINER DISPOSAL

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

# CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.





U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 401 M St., S.W. Washington, D.C. 20460

67727-2

NOTICE OF PESTICIDE: X Registration Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

JUL

2 1999

Term of Issuance:

Unconditional

Name of Pesticide Product:

1,4Sight Technical

Name and Address of Registrant (include ZIP Code):

D-I-1-4, Inc.

P.O. Box 860

Meridian, ID 83680

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) provided that you:

- 1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(2)(B) and section 4 when the Agency requires all registrants of similar products to submit such data.
  - 2. Make the following label change before you release the product for shipment:
- a. Revise the label by changing "EPA Reg. Number 67727-E" to "EPA Reg. No. 67727-2."

Signature of Approving Official:

Date:

JUL 2 1999

TA - see nextrag

Page 2 EPA Reg. No. 67727-2

3. Submit two (2) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution Prevention Division (7511C)

Enclosure

# 1,4SIGHT® TECHNICAL

### Aerosol Grade - Plant Growth Regulator

		By vveign
Active Ingredient:	1,4-Dimethylnaphthalene*	94.7%
		5.3%
TOTAL		100.0%
	active ingredient per gallon.	

## Keep Out of Reach of Children WARNING

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

### WARNING

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

### Statement of Practical Treatment

If in Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If Swallowed: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.

If on the Skin: Wash with plenty of soap and water. Get medical attention.

### **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

#### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

### See Directions for Use on Reverse

**Net Contents** 

Manufactured For;	
D-I-1-4, Inc.	
P.O. Box 860.	premium de la companya del companya del companya de la companya de

Meridian, ID 83680 USA

2 1999 JUL Under the Federal Inspeticide. Fungicide, and Redenticiide Act. as amended, for the pesticide registered under 67727 EPA Reg. No.

EPA Reg. Number 67727-E EPA Est. Number 68738-JPN-001°

Made in Japan. Revision 1

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during storage or use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

### PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

### PESTICIDE DISPOSAL

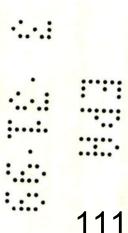
 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

### CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.





# SEPA United States Environmental Protection Office of Pesticide Programs

### Pesticide Regulation (PR) Notice 94-1

April 25, 1994

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, DISTRIBUTORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Withdrawal of PR Notice 91-8

Effective immediately, EPA is withdrawing PR Notice 91-8, entitled "Revised Policy To Provide Applicants Other Than Basic Manufacturers An Opportunity To Submit Generic Data and Receive Data Compensation For It." That notice requested the use of a generic label statement on manufacturing use products (MPs) to effect this policy. Persons who have complied with PR Notice 91-8 may retain such statements or may delete them from product labeling, at their discretion.

### I. BACKGROUND

In the mid-1980s, the Agency developed a policy for Manufacturing Use Product (MP) labeling that uses supported by the MP registrant should appear on the label and that reformulation for other uses should be prohibited. During pesticide reregistration many MP registrants have elected not to develop data in support of some label uses of their products, especially the minor uses. In accordance with Agency policy, these uses must be removed from MP product labeling.

Certain grower groups and end-use formulators have decided to fill the void themselves by submitting generic data to support the registration or reregistration of those minor uses. However, the Agency's policy for MP labeling could have the unintended consequence of denying these user groups and formulators compensation from other formulators for this data as provided under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Section 3(c)(1)(F). Because the Agency's MP labeling policy prohibits an unsupported use from appearing on an MP label, these user groups and formulators must provide the data they intend to generate to an MP registrant in order to ensure that an MP can be reformulated lawfully for the minor uses that the data support. Once the MP is supported for such uses, however, other formulators using the MP may claim the formulator's exemption for those uses, thereby denying compensation to the user groups or formulators that developed the data. Therefore, several end-use registrants and user groups requested that the Agency establish a mechanism to ensure that the data compensation rights of grower groups and formulators generating minor use data are retained.

PR Notice 91-8 was the Agency's attempt to ensure compensation for data developed by grower groups or formulators by requesting MP registrants to include an additional generic labeling statement that permits reformulation of their products for uses other than those specifically listed on the MP label and supported by the MP registrant, provided the formulator supports such uses. This statement preserves the data compensation rights of grower groups or end-use formulators because the labeling statement would effectively prevent other formulators that did not develop data from claiming the formulator's exemption for specific uses supported by user groups or end-use formulators.

These same end-use registrants and user groups have now advised the Agency that MP registrants should not be required to adopt the generic labeling statement set forth in PR Notice 91-8. These groups have joined with the representatives of MP registrants in advising the Agency that MP registrants should be able to control the uses made of their products by controlling the MP label. They indicated that the user groups and end-use formulators must work in cooperation with the MP registrants before developing the necessary data to sustain a use which the MP registrant no longer intends to support. These groups, have, however, asked that the Agency affirm that the formulators, coalitions,

manufacturers and grower groups that develop basic data are entitled to data compensation should another person rely on such data to obtain a registration.

### II. Agency Action

Because representatives of grower groups and end-use formulators who requested PR Notice 91-8 believe that the Agency should not require MP registrants to adopt the label statements set forth in the Notice, the Agency sees no reason to continue the policy. Accordingly, the Agency withdraws PR Notice 91-8 and will not require MP registrants to incorporate the generic labeling statement set forth in PR Notice 91-8.

### III. Data Compensation Rights of Persons who Develop Data

Although EPA is withdrawing PR Notice 91-8, it is not abandoning the principles underlying the notice. EPA affirms that data developers who develop generic or use-specific data in support of registration or reregistration of a product are entitled to the same data compensation rights as MP registrants that develop such data. They may request that they be identified on the Agency's Data Submitters List, as wanting data compensation from registrants who use their data in support of registration. The request to be added to the Data Submitters List should include the name of the active ingredient, data for which compensation is required, and their firm's name and address. Submit such requests to Ms. Sherada Hobgood at the address under VI below.

### IV. Registrant Action

MP registrants who have complied with PR Notice 91-8 may continue to use the label statement set forth in the notice, or may delete it at their discretion. No notification is required solely for this purpose.

Any MP registrants wishing to do so may add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of their product for a specific use or all additional uses supported by a formulator or user group. Furthermore, provided no other labeling changes are made, no notification to the Agency is required.

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such use(s)."
- (b) "This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such uses."

Note: This notice does not alter the Agency's basic labeling policy that MP registrants include a specific list on the label of those uses for which the MP may be reformulated.

### V. Effective Date

Effective immediately PR Notice 91-8 is withdrawn.

### VI. Additional Information

For further information please contact:

Rosalind L. Gross Registration Support Branch Registration Division (7505-W), EPA 401 M Street, SW Washington, DC 20460 (703) 308-8354 signed 4/25/94 by S.L.Johnson Stephen L. Johnson, Acting Director Registration Division (7505-C)

## PR notices | OPP Home | EPA Home | Search EPA | Comments

http://www.epa.gov/opppmsd1/PR\_Notices/pr94-1.html updated April 1, 1998





To: Denise Greenway/DC/USEPA/US@EPA

cc:

Subject: label statement question -Reply

we've in fact encouraged these sorts of statements (provided, of course, that the MP does in fact have at least one supported use). See PR Notices 91-8 and 94-1.

>>> < Greenway.Denise@epamail.epa.gov > 06/25/99 09:57am >>>

Hi, Mark

Please indicate your opinion of the following label statement. I think it is OK, but Phil Hutton doesn't like it. It appears on a pending Manufacturing Use

Product label, as a paragraph following the required statement telling what type

of products may be formulated from it..

"This product may be used to formulate products for any additional use(s) not

listed on the (product name) label if the formulator, user group, or grower has

complied with U.S. EPA submission requirements regarding the support of such use(s)."

Thanks for your comments. Enjoy the weekend!

Denise, 703 308-8263

# BPPD PRAT ACTION GODING FORM

					rcid 41.121
PM 90: Janet Anderser	1			STUBLOD	
EPA REG./FILE SYMBO	61727-E	(1	ASSIGNAU 82:	30019701	
ACTION CODE / 66		7	2	950 BMISSIO	^
SUBMISSION BARCODE	05010		r)		
Date on Application	3/30	199		Registr	ation
EPA Received Date	3/31/	19			
Received Date	4/1/	99			
Assigned in PRAT YES_	NC NC	D/	1		
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Manufacturing Use:	Yes N	<b>-</b>	- 0	rall amor add w	
Exclusive Use:	Yes N	•	The state of the s	y. Do both at	Andrews .

# Margery M. Exton

# Consultant Pesticide Regulatory Affairs

March 30, 1999

Denise L. Greenway
Biopesticides and Pollution Prevention Division
Mailcode 7511W
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Resubmission for Registration of EPA File Symbol 67727-E

1,4Sight Technical

Response to Agency Letter Dated 2/19/99

Dear Ms. Greenway:

On behalf of my client, D-I-1-4, Inc., I am submitting revised labeling in response to your letter identified above. We anticipate that this proposed label will meet with the Agency's satisfaction, as we have made all the previously requested changes. Upon clarification with the registrant, D-I-1-4, Inc. intends to package this product in 4.5, 5.0, and 50 gallon containers, and I have reflected this intention in a revised registration application form.

I would also like to note my client's preference to obtain concurrent registration of this product with registration of EPA file symbol 67727-G, 1,4Seed. Accordingly, we have maintained directions for use of this product for formulation into products for use on seed potatoes. We have revised the labeling to reflect all of the Agency's remaining comments.

We appreciate the Agency's thorough review and the consideration given to the registration of this product. Please contact me should you have questions about this application.

Margery Exton
Agent of Record
D-I-1-4, Inc.

Enclosures (1) Application Form

(2) Five Copies of Revised Label

cc: John Forsythe, D-I-1-4 Inc. Darol Forsythe, D-I-1-4 Inc.

~	Registration
	Amendment
	Other

<b>\$EPA</b>	Environmental Protect Washington, DC		icy	Amen Other	dment		
	Applica	ation for P	esticide - Se	ection I			
1. Company/Product Numb EPA File symbol 6772		1.	2. EPA Product M Denise Greenv	270		Proposed Cla	ssification Restricted
4. Company/Product (Nam 1.4Sight Technical	e)	10	<b>PM#</b> 90				
D-I-1-4, Inc. P.O. Box 860 Meridian, Idaho 836	pplicant (Include ZIP Code)		(b)(i), my producto:	leveiw. In accor	entical in c	omposition	
		Secti	on - II	,			
Amendment - Explain Resubmission in resubmission - Explain	sponse to Agency letter dated	<u>2/19/</u> 99	Final prin	nted labels in repso letter dated " Application. Explain below.			
Resubmission for registration	on in response to Agency letter, as n		on - III			199 for	6
1. Material This Product W	/ill Be Packaged In:						
Child-Resistant Packaging Yes No * Certification must be submitted	Unit Packaging  Yes  No  If "Yes"  Unit Packaging wgt.  No. per containe	If "Yes"	oluble Packaging les lo No. pe wgt contai	or .	Glass		
3. Location of Net Contents		Retail Containe 4.5, 5.0, and 5		5. Location of L		ions	
6. Manner in Which Label i	s Affixed to Product Little	hograph per glued enciled	Ot	her			
		Section	n - IV				
1. Contact Point (Complet	e items directly below for identifica	ation of individe	ual to be contacte	d, if necessary, to	process thi	s application	J
Name Margery M. Exton		Title Agent of F	ecord		Telephoi (703) 22	MARKET STATE OF THE STATE OF TH	de Area Code)
	ements I have made on this form a my knowlinglly false or misleading					6. Date Ap Receive	
2. Signature Margere	y Exter	3. Title Agent of Re	ecord				:::::•
4. Typed Name Margery M. Exton	9	5. Date	3-30-9	7		•::•	118

FEB 1 9 1999

Margery M. Exton 3719 Thomasson Crossing Drive Triangle, VA 22172

5557124

Dear Ms. Exton:

Subject:

1,4Sight Technical

EPA File Symbol 67727-E

Your Correspondence of October 1, 1998

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below.

trom response

- 1) The pending product is technical product intended for formulation into end-use products. Therefore, we question the wide range of packaging sizes declared on the EPA Form 8570-1, dated October 1, 1998. Please verify if your client will actually package this manufacturing-use product in the low range of container sizes listed on the form. If only the larger sizes will be used, a revised form must be submitted.
- 2) Because 1,4-dimethylnapthalene was described in the February 2, 1995, Fact Sheet as a plant growth regulator, the use of that term is acceptable to describe this pending manufacturing-use product, as well as the products which may be formulated from it. Registered formulated products for seed potato or transportation use do not currently exist, and so the word, "either" and the phrase, "...or transportation and use on seed potatoes" must be removed from paragraph two on page two of the label. However, because the Agency is in receipt of your December 10, 1998, application for a seed potato product (EPA File Symbol 67727-G), this pending manufacturing-use product may retain its reference to use on seed potatoes if you agree to concurrent registration of EPA File Symbols 67727-E and 67727-G. If concurrent registration of these two pending products is not acceptable, you must remove the seed potato and

transportation use references from the manufacturities use product label at this time. Upon registration of the seed potato end-use product, an antendment would be required to add the seed SYMBOL

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

potato use to the manufacturing-use product label. Please state your preference on this issue in your next submission.

- 3) We note that in the ingredients statement the term "Other Ingredients" has been replaced by "Inert Ingredients." This is acceptable. However, please be reminded that Pesticide Registration (PR) Notice 97-6 (enclosed) encourages the use of "Other Ingredients."
- 4) Under "Statement of Practical Treatment," please insert "steady" as the eighth word of the first sentence following the heading "If in Eyes." The revised sentence is to read, "Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes."
- 5) The company address appearing on the label must match the address of record in the Agency files. Based upon those records, the street address on the draft label must be replaced by. "P.O. Box 860" and the zip code must be replaced with "83680." Also in this section, replace the semicolon after the heading, "Manufactured For" with a colon.
- 6) The "Storage and Disposal" statement, "Do not reuse empty container" is acceptable provided that it is relocated to appear as sentence three under the subheading, "Container Disposal."

Please submit a label, revised as directed above, for further consideration. Should you have questions or concerns, please contact me, or telephone Denise Greenway on (703) 308-8263.

Sincerely,

Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution Prevention Division (7511C)

Enclosure

DGreenway/308-8263/2-5-99/exton14dmnletters.wpd/1,4-DMN

re acrosol

2/4/99 Roy restrict the flass
remarks like Dormany Engler 13 15 But he wrees that at class is the reduction the win that efficient dark an each

Margery M. Exton 3719 Thomasson Crossing Drive Triangle, VA 22172

production Consider

Dear Ms. Exton: .

Subject:

1,4Sight Technical

EPA File Symbol 67727-E

Your Correspondence of October 1, 1998

Sacaro RD mairo in macapot. latel

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) We note that in the ingredients statement, the term "Other Ingredients" has been replaced by "Inert Ingredients." This is acceptable. However, please be reminded that Pesticide Registration (PR) Notice 97-6 (enclosed) encourages the use of "Other Ingredients." check PR no and ensure not just for homeowner products 6k - it's an all products

) Under "Statement of Practical Treatment", please insert "steady" as the eighth word of the first sentence following the heading "If in Eyes." The revised sentence is to read, "Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes."

) The company address appearing on the label must match the address of record in the Agency files. Based upon those records, the street address on the draft label must be replaced by. "P.O.

118199 Peroline 1.18 5.1. 18 2/4 109 Phil - ret Jy est Itsel Leftont to the Editor

to track ...

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Box 860" and the zip code must be replaced with "83680." Also in this section, replace the semicolon after the heading, "Manufactured For" with a colon.

Is it ok for MUP to reference transportation products that are not yet registered? Seed potato use not yet reg., either... No. 200 Phil / Willie 2/4/55

Is label stmt re other uses OK? Philogy ck w/ Dyner. Willia o I thinge ok. leave as is for now - Since revisions are still needed, if Dyner specifies change it can be done always need oncle 214/99

) The "Storage and Disposal" statement, "Do not reuse empty container" is acceptable provided that it is relocated to appear as sentence three under the subheading, "Container Disposal."

Subject:

1 - 707-6

1,4Sight

EPA Reg. No. 67727-1

Your Correspondence of October1, 1998

Your EPA Form 8570-1, dated October1, 1998, requests that the product name be changed to "1,4Sight." This already is the product name of record (our March and July of 1998 letters erroneously included the proposed descriptive statement with the product name in the "Subject" lines).

We have considered your arguments for changing the product description from "sprout inhibitor" to "dormancy enhancer." The Biopesticides and Pollution Prevention Division (BPPD) recognizes that the delay of sprouting in stored potatoes may result in improved tuber quality and, subsequently, additional advantages to growers. The BPPD still objects, however, to the term, "enhancer." Acceptable alternative descriptive phrases include, "dormancy inducer," "lengthens dormancy," or "prolongs dormancy."

- ) Each of the proposed "Product Benefits" listed on the first page of the label are separated by the phrase, "[and/or]." This indicates that your client intends to select from the listed benefits when printing the label and marketing the product, perhaps directing product labeled with particular benefits to a specific market segment. This is acceptable provided that the first page of the label is revised to include as the first line the new heading, "Master Label."
- While the benefits list as described above is acceptable for master labels, the BPPD requires the revision of certain of those listed benefits. Because buds always are present on potatoes, the phrase "so no buds on potatoes" must be removed or revised. Although your letter reports that your client has found that 4.4-DMN aids in healing cuts and bruises and reduces pressure bruising of potatoes (through an unknown mechanism), we cannot accept the proposed label claim, "Helps control spread of potato rot." This statement could be construed as a fungicidal claim inappropriate for inclusion on the label of this plant regulator product, and as such may be

determined "false or misleading" under 40 CFR section 156.10 (a)(5) and the Federal Insecticide, Fungicide and Rodenticide Act section 2(q)(1)(A). Read Act cite a

### Await Janet's return from travel-she may obtain grower views on additional claims.

- ) Due to EPA's concerns regarding potential endocrine disruptors, it is advised that, to prevent the possibility of confusion, you revise the descriptive phrase on page one of the label (under "Product Benefits") from, "Naturally occurring hormone..." to, "Naturally occurring plant hormone..."
- ) Under "Statement of Practical Treatment", please insert "steady" as the eighth word of the first sentence following the heading "If in Eyes." The revised sentence is to read, "Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes."
- ) The company address appearing on the label must match the address of record in the Agency files. Based upon those records, the street address on the draft label must be replaced by. "P.O. Box 860" and the zip code must be replaced with "83680." Also in this section, replace the semicolon after the heading, "Manufactured For" with a colon.
- ) The "Storage and Disposal" statement, "Do not reuse empty container" is acceptable provided that it is relocated to appear as sentence three under the subheading, "Container Disposal."
- As per the BPPD decision of item, above, the "Directions for Use" section phrases, "dormancy enhancer" and "enhance the dormancy" must be replaced with acceptable alternative text.
- ) Your replacement of "applicators" with the more accurate term, "workers" is acceptable.
- ) Pesticide Registration (PR) Notice 98-9 (enclosed) calls for the modification of certain respirator label language. The new language is required to be added to affected pesticide product labels by April 1, 2000. Adding the new text at this time will obviate the need for its separate addition by notification. Please consult the enclosed PR Notice for more details. Please add to the existing respirator recommendations (which appear in two locations on the subject label) the following: ", or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter."
- ) Storage facilities are referred to in the label by either the term "storage area," or simply, "storage." It is suggested that for clarity and uniformity the term "storage area" be used throughout the label.
- ) We note that the 90-day period specified in the September 9, 1997, draft label, during which vapors should not be allowed contact with seed potato storage areas (last "bullet" under "Notice"), has been reduced to 60 days. This 60-day period matches the time period specified in the new, pending 1,4Seed label (EPA File Symbol 67727-G). The unannounced change is acceptable.

- ) Replace the semicolon with a colon in item three of "Treatment of Storage Areas That Do Not Have Recirculating Air Systems."
- ) The first five lines on page three of the draft label are duplications of text from the preceding page and must be deleted.
- ) We note that the 24-hour waiting period preceding fresh air introduction to treated storage areas has been reduced to 12 hours. This unannounced change is acceptable, but is mentioned in the event that it was inadvertent.

1-10 sine

Subject:

1,4Seed

EPA File Symbol 67727-G

Your Correspondence of December 10, 1998

) You state that the formulation of this pending product is indentical to that of EPA Reg. No 67727-1. Comparison of the two Confidential Statement of Formula (CSF) forms indicates that the form submitted for this pending product matches the EPA Reg. No 67727-1 CSF of December 21, 1993. The 1993 form was replaced with an acceptable, revised CSF dated September 21, 1994. The CSF for this pending product must, therefore, be revised to match the current EPA Reg. No 67727-1 CSF.

Ne have considered your arguments (presented in your October 1, 1998, amendment for EPA Reg. No 67727-1) for changing the product description from "sprout inhibitor" to "dormancy enhancer." The Biopesticides and Pollution Prevention Division (BPPD) recognizes that the delay of sprouting in stored potatoes (including stored seed potatoes) may result in improved tuber quality and, subsequently, additional advantages to growers. The BPPD still objects, however, to the term, "enhancer." Acceptable alternative descriptive phrases include, "dormancy inducer," "lengthens dormancy," or "prolongs dormancy."

) Each of the proposed "Product Benefits" listed on the first page of the label are separated by the phrase, "[and/or]." This indicates that your client intends to select from the listed benefits when printing the label and marketing the product, perhaps directing product labeled with particular benefits to a specific market segment. This is acceptable provided that the first page of the label is revised to include as the first line the new heading, "Master Label."

) While the benefits list as described above is acceptable for master labels, the BPPD requires the following revision. Although your October 1, 1998, letter reported that your client has found 1,4-DMN to aid in healing cuts and bruises and to reduce pressure bruising of potatoes (through an unknown mechanism), we cannot accept the proposed label claim, "Helps control spread of potato rot." This statement could be construed as a fungicidal claim inappropriate for inclusion on the label of this plant regulator product, and as such may be determined "false or misleading" under 40 CFR section 156.10 (a)(5) and the Federal Insecticide, Fungicide and Rodenticide Act

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section 2(q)(1)(A). Read Act cite

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- ) Under "Statement of Practical Treatment", please insert "steady" as the eighth word of the first sentence following the heading "If in Eyes." The revised sentence is to read, "Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes."
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- ) Storage facilities are referred to in the label by either the term "storage area," or simply, "storage." It is suggested that, for clarity and uniformity, the term "storage area" be used throughout the label.

Likewise, you may wish to substitute "seed potato" for "potato" throughout this specialty label.

Should you have questions or concerns, please contact me, or telephone Denise Greenway on (703) 308-8263.

Sincerely,

Janet L. Andersen, Ph.D. Director Biopesticides and Pollution Prevention Division (7511C)

Enclosures (2)

DGreenway/308-8263/1-8-99/exton14dmnletters.wpd/1,4-DMN

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAR 18 1998

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Edgar R. Butts, Ph.D.
E. R. Butts International, Inc.
26 Sherman Court
P.O. Box 764
Fairfield, CT 06430

1/5/99 letter versein ok base next letter on label markup 8/15/1/98 pp version

Dear Mr. Butts:

SUBJECT: 1,4Sight Technical Aerosol Grade

Potato Dormancy Enhancer EPA File Symbol No. 67727-E

Your Correspondence of December 2, 1997, and

February 6, 1998

Your December, 1997, correspondence sought a section 3 registration for a technical formulation that is identical to that of your client's registered end-use product, EPA Reg. No. 67727-1. Your February, 1998, submission consisted of the revised Confidential Statement of Formula (CSF) and EPA Form 8570-1, as requested by the Biopesticides and Pollution Prevention Division (BPPD) during a phone call on February 5, 1998. The February submission is a satisfactory correction of both documents. Also, your December, 1997, letter has been annotated to indicate the correct percentage (94.7%) of active ingredient.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below. Please revise the proposed label as described and resubmit it for further review.

- 1) Replace "Dormancy Enhancer" with "Sprout Inhibitor" in the product name.
- 2) The signal word ("Warning") must be relocated to appear on a single line below the statement, "Keep Out of Reach of Children."

The label's Precautionary Statements and Statement of Practical Treatment must reflect the Toxicity Categories assigned to the acute toxicity data submitted in support of EPA Reg. No. 67727-1. The BPPD has determined that the Toxicity Category originally assigned to the acute dermal toxicity study (MRID 430825-11) must be corrected from IV to III. Based on this, and the results of the other studies (acute oral, III; acute inhalation, IV; primary eye irritation, II; primary skin irritation, IV; dermal sensitization, negative), the proposed label must be revised.

Replace the existing "Precautionary Statements" with,
"Causes substantial but temporary eye injury. Harmful if
swallowed or absorbed through skin. Do not get in eyes or on
clothing. Wear protective eyewear (goggles or face shield).
Avoid contact with skin. Wash thoroughly with soap and water
after handling. Remove contaminated clothing and wash clothing
before reuse."

Under the "Statement of Practical Treatment" heading, update the "If in Eyes:" text by removing the existing first sentence. Add as the second sentence, "Get medical attention."

Update the "If Swallowed:" text by inserting as sentences one and two, "Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person." Revise the existing sentence by pluralizing "egg white" and inserting "drink" immediately before the second occurrence of the word "large."

Update the "If on Skin: " text to, "Wash with plenty of soap and water. Get medical attention."

- 4) The BPPD requires that the "Environmental Hazards" section be revised by adding as new paragraph one, "This product is highly toxic to freshwater fish and aquatic invertebrates."
- 5) The phrase, "Storage and Disposal," may be deleted from the front panel statement appearing immediately above "Net Contents" because that section is a part of the "Directions for Use."
- 6) Replace "dormancy enhancer" with "sprout inhibitor" in the third line of the "Directions for Use" section.
- 7) In the "Storage and Disposal" section, change the subheading "Storage" to "Pesticide Storage." Relocate the sentence, "Do not contaminate water, food, or feed by storage or disposal." to appear directly under the "Storage and Disposal" main heading. Delete the first sentence under "Container Disposal."

The proposed label must be revised as described above and submitted for further review. You are invited to fax the revision [(703) 308-7026] to expedite the process. Should you have questions or concerns, please write, or contact me on [(703) 308-8263].

Sincerely,

Denise L. Greenway

Regulatory Action Leader
Biopesticides and Pollution
Prevention Division (7511W)

Nancy Fitz DFEAD contains oute (Amy Breedlose called her) says text of proposed is of add at one of regular cont. disp statement apole ul wille re glashi + metal checked on form Sul test for metal container disposed only is used on labels We decided that this is OK since burning of plastics is often undescreable. Willie will earnel Many whis view that the plastics burging recommendation be regarded du to the is ble for motion of toxic fines Amy Breedlove 5+D no new text jut, but under development 308 9069 / AME

# BPPD PRAT ACTION GODING FORM

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Exclusive Use:	Yes	No			4-11	

# Margery M. Exton Consultant

**Pesticide Regulatory Affairs** 



October 1, 1998

Denise L. Greenway Biopesticides and Pollution Prevention Division Mailcode 7511W U. S. Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460

Subject: Resubmission for Registration of EPA File Symbol 67727-E

1,4Sight Technical

Response to Agency Letters Dated 3/18/98 and 7/28/98

Dear Ms. Greenway:

180.1142

On behalf of my client, D-I-1-4, Inc., I am submitting revised labeling in response to your letters identified above. We hope that these proposed labels for a 1,4Sight Technical product will meet with the Agency's satisfaction. Nearly all of the Agency's previous comments have been incorporated verbatim. However, my client preferred the more generic term "plant growth regulator" in describing this product and the uses into which this product could be formulated to the Agency's suggestion of "sprout inhibitor(s)."

Additionally, the Agency had requested that the sentence "Do not reuse as a container" be removed from the label. We agree that this statement had previously been placed in an inappropriate section of the label. We have revised the wording of this statement to better reflect our intention and have placed the statement below the subheading "Storage and Disposal." The statement now reads "Do not reuse empty container." D-I-1-4 Inc. wishes, for the reasons noted below, to maintain this statement on all registrations of products sold in containers which could feasible be reused.

My client does not believe it is environmentally sound to use an empty pesticide container for purposes of storage of another material. Beyond the issue of the health and safety of such a practice, my client has concerns regarding the possible confusion as to whether the container. holds the registered material and the possibility of a foreign material being use a coordinate of D-I-1-4 label directions. Consequently, we wish to avoid this practice and reduce any subsequent liability.

We are aware of situations, where, in the absence of such a statement, a user has personally "recycled" pesticide containers for their own purposes. In a recent case, a state attorney general

as last senting,

and the Agency were unable to enforce against this, since an empty container does not fall within the meaning of a pesticide under FIFRA.

We note that this statement now occurs on many registered pesticides, and is included in the Agency's proposed Disposal Rule as a recommendation to lessen a label's ambiguity on this subject. For these reasons, D-I-1-4 Inc. requests to be allowed to include this statement on their it allowed is placement correct? No-relocate labels.

I have enclosed a completed application form, along with five copies of the proposed labeling. I am available to discuss any issues regarding this application on (703) 221-4383. Thank you in advance for your thorough review and consideration of this application.

Sincerely,

Margery Exton Margery M. Exton Agent of Record

D-I-1-4, Inc.

Enclosures

(1) Application Form

(2) Five Copies of Revised Label

John Forsythe, D-I-1-4 Inc.

Darol Forsythe, D-I-1-4 Inc.

October 1, 1998

Margery M. Exton

12/18/98 mark-up

# 1,4SIGHT® TECHNICAL

Aerosol Grade - Plant Growth Regulator

	by weigh
Active ingredient: 1,4-Dimethylnaphthalene*	94.7%
Inert ingredients:	5 3%
TOTAL had ween o Her" are 1987 PR	100.0%
* Contains 7.9 pounds active ingredient per gallon.	

# Keep Out of Reach of Children

## WARNING

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

## WARNING

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Statement of Practical Treatment

If in Eyes: Hold eyelids open and flush with a gentle stream of water for 15 minutes. Get medical attention.

If <u>Swallowed</u>: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.

If on the Skin: Wash with plenty of soap and water. Get medical attention.

**Emergency Information** 

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See Directions for Use on Reverse

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EPA Reg. Number 67727-E EPA Est. Number 68738-JPN-001 Made in Lapan © /c Revision 1

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#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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Only for formulation into plant growth regulators for use on post-harvest potatoes during either storage or transportation and use on seed potatoes.

15 transport of 2 No pending or current latels not that use yet

or ck will

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

# STORAGE AND DISPOSAL Kind of conflicts w/ offer

Do not contaminate water, food, or feed by storage or disposal. Do not reuse empty container.

### PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

### PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

form says

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
 OK for regal and fold but for plashis there are burning instructions

ask Label unit or Anil Metal text may be ok Ar both > use as is, burning plashes can be hazardous (fumes

### **CONDITIONS OF SALE**

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

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# 1,4SIGHT® TECHNICAL

### Aerosol Grade - Plant Growth Regulator

	В	/ Weight
Active ingredient:	1,4-Dimethylnaphthalene*	94.7%
Inert ingredients:		5.3%
TOTAL		100.0%
Contains 70 nounds a	active ingredient per gellen	

# Keep Out of Reach of Children

## WARNING

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

### WARNING

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

### Statement of Practical Treatment

If in Eyes: Hold eyelids open and flush with a gentle stream of water for 15 minutes. Get medical attention.

If Swallowed: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.

If on the Skin: Wash with plenty of soap and water. Get medical attention.

### **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

### **Environmental Hazards**

This product is highly toxic to freshwater fish and aquatic invertebrates.

Meridian, ID 83642 USA

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See Directions	for Use on Reverse
Net Con	itents
	· · · · · ·
Manufactured For;	EPA Reg. Number 67727-E
D-I-1-4, Inc.	EPA Est. Number 68738-JPN-001
2307 E. Commercial St.	Made in Japan

·Revision.1

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into plant growth regulators for use on post-harvest potatoes during either storage or transportation and use on seed potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight<sup>®</sup> Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Do not reuse empty container.

### PESTICIDE STORAGE

Keep container closed. This product temporarily inhibits germination of seed potatoes.

### PESTICIDE DISPOSAL

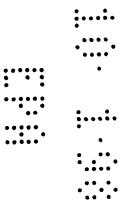
 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### **CONTAINER DISPOSAL**

 Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

### **CONDITIONS OF SALE**

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



ROUTING AND	TRANSMITTAL SLIP	Date 9	1/29	//	
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4.				*	
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FROM: (Name, org. symbol, Agency/Post)	Room No.—Bidg.
Panal	Phone No. 308 8 263
5041-102	OPTIONAL FORM 41 (Rev. 7-76) Prescribed by GSA EPHA (41 CER) 101-11 206

Margery Exten for 1.4 Soflet 19/1/98
3 submissions made today ) 1.4 Sight
2) tech result 3) I for Seed New product
Win 2 wks expect 1/4 Slip" for framsport of potatoes
recall chlosporghu 1,4DMV int as sum lan to Kut as they they but a added chains (above be yould sport in h. b. for)
Induced darming to delay buds  Co wonts dorman enhance - See cover letter  "Roy challenger, "horizon" as a condicional doscription of uses of all claims are new by chilly is himmed sine endorse delay.
doscription of uses all claims are new by chilleges himmer sive endicate
ched loted for chlorprophon - we think it says spront into sifes.
Ry my preter "plant hamme" rather than 'harmone'
Naves - see letter just 14 Sight"
contame disposed - locks like today roasty per > relocate this
140

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Ry-Rad to ague this w/o data esp for eyes RS of need

No peat, world get need to repeat the lige, but others in 6 peach

different wests - RS do the study w/eyes \* different wests - RS do the study weeps \* seed potatoes of rez product now o are in separate file symbol use in tech the used PGR rather than "dorning enhancer"
PS for "home" my went PGR there, too Told he PR is preferred

# Talking Points for D-I-1-4 Submissions

Today 1,4Sight 1,4Sight Technical 1.4Seed **Future** 1,4Ship

Initially, 1,4-DMN thought of as "like CIPC." in use pattern, and consequently benefits. But learning about the product's true "niche" through use, and wish to label accordingly. There are major differences between the products and their benefits. Most of those benefits are not on the label now.

Most Agency comments have been addressed outright, so no need to mention today. Three items noted by Agency where we have deviated, as shown below.

1. Still wish to add claims regarding enhancement of the dormant stage of the potato. Added marketing claims to describe benefits significant to users, which are not necessarily "pesticidal." Company is hopeful to market the product in this way, probably without including the claims on the final, printed labeling. [Space constraints -- Format of proposed labels]

Major shift from CIPC niche to 1,4-DMN use lies in the difference between inhibiting sprouts by destroying cells in the bud versus actually delaying sprouting. This results in an improved appearance of the potato when it exits storage, which is an advantage in the marketplace. Since the potatoes aren't using energy to sprout, they respire less, resulting in less water loss from the tuber. This is another marketplace advantage, since they weigh more, will be firmer, and can be sold for a higher price. Reduced respiration means that the storage facility itself will be cooler and contain less carbon dioxide, placing fewer refrigeration and ventilation demands on the system.

Through an unknown mechanism, the hormone aids the potato in healing cuts and bruises, reducing pressure bruising in the potato. With fewer open wounds, potatoes are also less

(What does Agency have on file as product name?) the name the want is official name of the product name?) the name the want is official name of the product name?)

Want "empty container" statement and the product name?)

EPA enforce against it, and draft disposal Rule suggests labels add the statement. new text ot, but relocate

3. Broadened reentry PPE language from "applicators" to "workers" to reflect actual practices. 0 1/2

In addition, these are changed labels from those last reviewed. Again, refined Directions for Use, modified equivalency table to be more useful in potato industry, introduced maximum application rates. Moving to more frequent applications at lower rates.

!,4Seed Label very similar to 1,4Sight label in terms of rates and usage. Current practice on seed potatoes versus proposed use - potato uses up less of it's energy, if it hasn't sprouted until the planned germination/planting in spring.

1,4Ship Label - coming in soon. Aerosol can (like hairspray) with about 10% a.i. and propellant inert. Post-storage phase - while potatoes packaged for shipment. (Trucks, cargo containers) Very close to 10 fold dilution, so initial proposed label as "Caution." Maximum application rate of 10 ppm product to potato.

We'd be happy to come in and discuss any of the proposed changes further, should you want more information.

# D-I-1-4

NODE 8/3/98

P.O. Box 860, Meridian, ID 83680-0860 Phone (208)887-9766 Fax (208)887-1467

July 27, 1998

Ms. Denise L. Greenway
Biopesticides and Pollution Prevention Division (7511W)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

VIA FAX and USPS

Re: D-I-1-4, Inc Agent of Record

Dear Ms. Greenway:

I am requesting that you make Margery M. Exton our Agent of Record as of this date. Ms. Exton can be reached on (703) 221-4383, and correspondence to her addressed to 3719 Thomasson Crossing Drive, Triangle, Virginia, 22172. Please contact me if you have any questions regarding this request.

Sincerely,

John Forsythe

JF/sm

cc: Margery M. Exton

## JUL 30 1998

Ms. Margery M. Exton 3719 Thomasson Crossing Dr. Triangle, VA 20460

Dear Ms. Exton:

Subject:

1,-4Sight Aerosol Grade Potato Dormancy Enhancer

EPA Reg. No. 67727-1

1,4Sight Technical Aerosol Grade Potato Dormancy Enhancer

EPA File Symbol 67727-E

As per Mr. John Forsythe's enclosed fax of July 27, 1998, you are identified the new agent of record representing his company, D-I-1-4. Therefore, I am enclosing recent correspondence from the Agency, dated July 27 and 28, 1998, for your attention.

Should you have any questions or concerns, please telephone me on (703) 308-8263.

Sincerely,

Denise Greenway

Regulatory Action Leader Biopesticides and Pollution

Prevention Division (7511C)

Enclosures

DGreenway/308-8263/7-30-98/EXTON.LTR/1,4-DMN

CONCURRENCES								
SYMBOL		7511W						
SURNAME		NO1509		1				
DATE		7/30/98						145
EPA Form 1320-1A (1/90)			Printed on Recycled Paper					AL FILE COPY

7/30/98

Mr. Forsythe,

7128/98 m67727-E and 7127/98 7127/98 Please accept my apologies
for having misdirected the
first mailing of these two letters
to your former address. For
your information, I have also
forwarded copies to your new
agent of record, Ms. Exten, and
have taken steps to update
our records to reflect this
change in representation. Should
you have concerns, please
contact me.

Sincerely, Sonic Greenwy, BPPD (703) 3088263 D-I-1-4

P.O. Box 860, Meridian, ID 83680-0860 Phone (208)887-9766 Fax (208)887-1467

July 27, 1998

Ms. Denise L. Greenway
Biopesticides and Pollution Prevention Division (7511W)
U.S. Environmental Protection Agency
40. M Street, S.W.
Washington, DC 20460

VIA FAX and USPS

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Sincerely,

John Forsythe

JF/sm

cc: Margery M. Exton

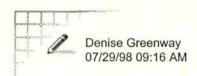
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P.01

JUL-29-1998 17:06

208 887 1467

95%



To:

Janet Andersen/DC/USEPA/US, Roy Sjoblad/DC/USEPA/US

CC:

Subject: 1,4-DMN letters

I called Ed Butts to alert him of the recently prepared letters. Although he had repeatedly stated that his intention was to help this client respond to the March requirements, it turns out that he will give up the 1,4-DMN account. He informed me that Margery Exton (no longer with the Agency) will take over as consultant, and that he will assist as needed.

I requested that the Agency be formally notified of the change in representation. Upon receipt of such documentation, I will forward copies of our letters to the new consultant.

FYI

JUL 28 1998

Edgar R. Butts, Ph.D. E. R. Butts International, Inc. 26 Sherman Court P. O. Box 764 Fairfield, CT 06430

Dear Dr. Butts:

SUBJECT:

110.

1,4Sight Technical Aerosol Grade Potato Dormancy Enhancer EPA File Symbol No. 67727-E

Your Application of December 2, 1997

Your December, 1997, correspondence sought a section 3 registration for a technical formulation that is identical to that of your client's registered end-use product, EPA Reg. No 67727-1. At our request, on February 6, 1998, you submitted a revised Confidential Statement of Formula and EPA Form 8570-1 for the subject application.. On March 18, 1998, the Biopesticides and Pollution Prevention Division (BPPD) issued a letter (enclosed) notifying you that the revisions were satisfactory, and advising you of deficiencies in the proposed label for EPA File Symbol 67727-E. To date, we have received no response to the March label review letter.

This application will be kept open for a period of 75 days (from the date of this letter) to give you an opportunity to correct the deficiencies listed in the BPPD letter of March 18, 1998. If you find that more time is necessary to meet the requirements, you must request an extension and commit to resolve the deficiencies within a reasonable, stated, period of time. If you do not comply, the Agency may administratively withdraw this application from further consideration and retire this file without notice to you, in accordance with the policy established by PR Notice 75-4 of August 27, 1975. Should this occur, you will have to submit a complete new application if you wish to pursue the registration of this pending product after this application has been withdrawn.

CONCURRENCES								
SYMBOL	75110	2511						
SURNAME )	Greenway	Barbol						
DATE	7/27/98/	2/22/78						149
EPA Form 1320-1A (1/90)		Printed on Recycled Paper				OFFICIAL FILE COPY		

Should you have questions or concerns about this letter, please contact me, or telephone Denise Greenway on (703) 308-8263.

Sincerely,

Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution Prevention Division (7511C)

Enclosure

cc: John Forsythe, D-I-1-4

DGreenway/308-8263/07-24-98/BUTTS75.LTR/1,4-DMN

ROUTING AND TRANSMITTAL SLIP 7/27/98									
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Coordination	Justify								
pending section 3 application  I alerted the consultant previously to the label deficiencies for this application  I failed to institute the 75-day limit in my 1st letter. Although the consultant has repeatedly promised a reply, nore has									
been received. This letter buts them on notice for the 75-day limit. The registrant									
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5041–102  OPTIONAL FORM 41 (Rev. 7–76)  Prescribed by GSA FPMR (41 CFR) 101–11.206									

MAR 18 1998

5535 176 5539394 166 12

Edgar R. Butts, Ph.D.
E. R. Butts International, Inc.
26 Sherman Court
P.O. Box 764
Fairfield, CT 06430

Dear Mr. Butts:

SUBJECT: 1,4Sight Technical Aerosol Grade

Potato Dormancy Enhancer EPA File Symbol No. 67727-E

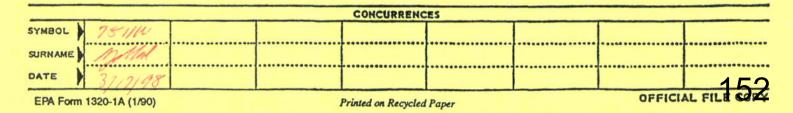
Your Correspondence of December 2, 1997, and

February 6, 1998

Your December, 1997, correspondence sought a section 3 registration for a technical formulation that is identical to that of your client's registered end-use product, EPA Reg. No. 67727-1. Your February, 1998, submission consisted of the revised Confidential Statement of Formula (CSF) and EPA Form 8570-1, as requested by the Biopesticides and Pollution Prevention Division (BPPD) during a phone call on February 5, 1998. The February submission is a satisfactory correction of both documents. Also, your December, 1997, letter has been annotated to indicate the correct percentage (94.7%) of active ingredient.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below. Please revise the proposed label as described and resubmit it for further review.

- 1) Replace "Dormancy Enhancer" with "Sprout Inhibitor" in the product name.
- 2) The signal word ("Warning") must be relocated to appear on a single line below the statement, "Keep Out of Reach of Children."



Edgar R. Butts, Ph.D.
E. R. Butts International, Inc.
26 Sherman Court
P.O. Box 764
Fairfield, CT 06430

Dear Mr. Butts:

SUBJECT: 1,4Sight Technical Aerosol Grade
Potato Dormancy Enhancer
EPA File Symbol No. 67727-E

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February 6, 1998

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- 1) Replace "Dormancy Enhancer" with "Sprout Inhibitor" in the product name.
- 2) The signal word ("Warning") must be relocated to appear on a single line below the statement, "Keep Out of Reach of Children."

The label's Precautionary Statements and Statement of Practical Treatment must reflect the Toxicity Categories assigned to the acute toxicity data submitted in support of EPA Reg. No. 67727-1. The BPPD has determined that the Toxicity Category originally assigned to the acute dermal toxicity study (MRID 430825-11) must be corrected from IV to III. Based on this, and the results of the other studies (acute oral, III; acute inhalation, IV; primary eye irritation, II; primary skin irritation, IV; dermal sensitization, negative), the proposed label must be revised.

Replace the existing "Precautionary Statements" with, "Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse."

Under the "Statement of Practical Treatment" heading, update the "If in Eyes:" text by removing the existing first sentence. Add as the second sentence, "Get medical attention."

Update the "If Swallowed:" text by inserting as sentences one and two, "Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person." Revise the existing sentence by pluralizing "egg white" and inserting "drink" immediately before the second occurrence of the word "large."

Update the "If on Skin:" text to, "Wash with plenty of soap and water. Get medical attention."

- 4) The BPPD requires that the "Environmental Hazards" section be revised by adding as new paragraph one, "This product is highly toxic to freshwater fish and aquatic invertebrates."
- 5) The phrase, "Storage and Disposal," may be deleted from the front panel statement appearing immediately above "Net Contents" because that section is a part of the "Directions for Use."
- 6) Replace "dormancy enhancer" with "sprout inhibitor" in the third line of the "Directions for Use" section.
- 7) In the "Storage and Disposal" section, change the subheading "Storage" to "Pesticide Storage." Relocate the sentence, "Do not contaminate water, food, or feed by storage or disposal." to appear directly under the "Storage and Disposal" main heading. Delete the first sentence under "Container Disposal."

The proposed label must be revised as described above and submitted for further review. You are invited to fax the revision [(703) 308-7026] to expedite the process. Should you have questions or concerns, please write, or contact me on [(703) 308-8263].

Sincerely,

Denise L. Greenway

Regulatory Action Leader Biopesticides and Pollution Prevention Division (7511W)

DGreenway/308-8263/3-9-98/BUTTSTEK.LTR/1,4-DMN/55802

BUTTS TER. LTR

Edgar R. Butts, Ph.D.

Edgar R. Butts, Ph.D.

Butts International Inc.

3/5/98

BUTTS TER. LTR

to Roy for concurrence
3/16/98

Edgar R. Butts, Ph.D.
E. R. Butts International, Inc.
26 Sherman Court
P.O. Box 764
Fairfield, CT 06430

Dear Mr. Butts:

SUBJECT: 1,4Sight Technical Aerosol Grade Potato Dormancy Enhancer

EPA File Symbol No. 67727-E

Your Correspondence of December 2, 1997, and February 6, 1998

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The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below. Please revise the label as described and resubmit it for further review.

- ) Replace "Dormancy Enhancer" with "Sprout Inhibitor" in the product name.
- ) The signal word ("Warning") must be relocated to appear on a single line below the statement, "Keep Out of Reach of Children."
- ) Revise the "Precautionary Statements" to omit the phrase "on skin" from the third sentence. Revise sentence four to read, "Wear protective eyewear (goggles or face shield.)" Remove the

phrase "...and before eating, drinking or using tobacco." from sentence five. Revise the last sentence to become, "Remove contaminated clothing and wash clothing before reuse."

) Update the "If in Eyes:" text by removing the existing first sentence. Add as the second sentence, "Get medical attention."

Update the "If Swallowed:" text by inserting as sentences one and two, "Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person."

Remove the "If on Skin:" text and heading. check with Roy on Carol's opinion that the acute dermal is really III and not IV as reported on fact sheet and in Cindy's review, then write text as approp. for tox III for stmt of pract trtmt and precaut stmtsmay req alteration of JS advice on appl/Early entry gear, too if tox cat is changed

- ) Note to Physician explain issues to Roy; see if he wants it or not
- ) Update the "Environmental Hazards" section by find out if fish/ag invert stmt should be used yes sent to misse to file to a EP
- ) The phrase, "Storage and Disposal," may be deleted from the front panel statement appearing immediately above "Net Contents" because that section is to become a part of the "Directions for Use" section. See item \_\_\_\_, below.
- The "Storage and Disposal" section must be relocated to appear in the "Directions for Use" section, near either the beginning or the end of that section. Change the subheading "Storage" to "Pesticide Storage." Relocate the sentence, "Do not contaminate water, food, or feed by storage or disposal." to appear directly under the "Storage and Disposal" main heading. Delete the first sentence under "Container Disposal."
- ) Replace "dormancy enhancer" with "sprout inhibitor" in the third line of the "Directions for Use" section.

The proposed label must be revised as described above and submitted for further review. You are invited to fax the revision [(703) 308-7026] to expedite the process. Should you have questions or concerns, please write, or contact me on [(703) 308-8263].

Sincerely,

Denise L. Greenway Regulatory Action Leader Biopesticides and Pollution

Prevention Division (7511W)

1,4,DMN w/Ray

MEYES (for II) & Note to Physician

Label Tean said no inste to Phys for for II eyes any longer

No Note as per Ray

Wear cluthy for fell 24 horrs (prior to intro of Bresh air)

Roy agrees that acute dermal shall be
III & not It as appears in Rete of

fact Sheet

refigure clothy using tox TI text

Ry said seed potato kat in lotter is OK

· Alert Rey that acute dermal is II, not II & redo label accordingly

· Hore workers wear " reenty" year outil fresh air is introduced, not just til fog clears

" Roy agrees that no note to physician is regumed; the eye data aren't very bad

. He thinks my draft letter text on seed potato use is o'k reflection of AARC concerns

· For the new tech, he suggests keeping the fish/ag invert. hazand stint on the tech, as it appears on the EP, even the both prod. are used in side

# BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen		REVIEWER:		
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Manufacturing Use: Y	'es N	lo		
Exclusive Use: Y	/es	lo		

## E.R. BUTTS INTERNATIONAL, INC.

26 Sherman Court P.O. Box 764 Fairfield, CT 06430 Telephone: 203-256-0460

Fax: 203-256-0464

Via Federal Express - Standard

RECEIVED

February 6, 1998

FFB 1 7 1998

Ms. Denise Greenway (PM-90) Biopesticides and Pollution Prevention Division Office of Pesticide Programs **Environmental Protection Agency** Room 266A, Crystal Mall 2 1921Jefferson Davis Highway Arlington, VA 22202

OPP/BPPD

Subject:

1,4SIGHT Technical – Aerosol Grade – Potato Dormancy Enhancer

EPA File Symbol - 67727-E

Follow-up to Our Telephone Discussion of February 5, 1998

## Dear Denise:

This letter is a follow-up to our telephone discussion of yesterday. Thank you very much for bringing these points to my attention. I have enclosed corrected forms as follows per our discussion:

- Application for Pesticide Other (EPA Form 8570-1)
- Confidential Statement of Formula (EPA Form 8570-4)

I apologize for the error.

Should you have any questions or comments, please contact me. Thank you for your continued assistance.

Sincerely.

Edgar R. Butts, Ph.D.

Regulatory Consultant and Authorized Agent for D-I-1-4, Inc.

CC: Mr. Darol Forsythe, President, D-I-1-4, Inc.

Mr. John Forsythe, General Manager, D-I-1-4, Inc.

Please instructions on	reverse before comple	ting form.	Fo	rm Approve	d. OMB No. 207	70-0060	D. Approval expires 2-28-9
<b>ŞEPA</b>	ı	Inited States	ection Agency		Registrati		OPP Identifier Number
<b>YEFA</b>		ngton, DC 204			Amendme Other	ent	215969
		Application	n for Pesticide -	Section	H		
1. Company/Product Numbe 67727-E	,		2. EPA Produ Denise G	Charles of the Control of the Control			pposed Classification
4. Company/Product (Name) D-I-1-4, Inc./1	nical	PM#0 Restricted					
	B3680-0860 USA			No.			FIFRA Section 3(c)(3) mposition and labeling
		711	Section - II	y e			
Notification - Explain  Explanation: Use addition	onse to Agency letter below. nal page(s) if necessar updated contai	y. (For section	Agei "Me  X Other  I and Section II.)  and confidenti	ncy letter da Too" Appli er - Explain b	pelow.		a.
1. Material This Product Wil		revisi	Section - III			2	
Child-Resistant Packaging Yes No	Unit Packaging Yes No		Water Soluble Packag Yes X No	jing	X F	Metal Plastic Glass	
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container					
3. Location of Net Contents  X Label C  6. Manner in Which Label is	ontainer	55.0 gal	all Container cers, 200 Liters and bulk	5. L	ocation of Label	Directio	ns
		X Paper Stenci	glued led			1	
		1 1	Section - IV				
1. Contact Point (Complete	items directly below	for identificatio	n of individual to be cont	tacted, if ne	cessary, to proce	ss this	application.)
Name Edgar R. But	ts, Ph.D.		Title Agent & Regu	ulatory			No. (Include Area Code)
	y knowlinglly false or	misleading sta	all attachments thereto dement may be punishab	le by fine or	r imprisonment o	r	6 Date Application Received (Stamped)
Edjan	R But		3. Title Agent & Reg	gulatory	Consultan	С	•::•
4. Typed Name Edgar	R. Butts		5. Date 2/06/98				<mark>1</mark> 62

## PAPERWORK REDUCTION ACT MOTICE and INSTRUCTIONS



PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 N Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

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1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4);

3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted;

6. Authorization letter where applicable; 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

 $\underline{SECTION\ I}$  - This section must be completed, as applicable, for all registration actions.

 Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned
to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.

2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include

any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be

similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach

a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types.

• Indicate the size of the individual packets and number per retail container.

2. Type of Retail Container - Indicate type of container in which product will be marketed.

3. Legation of Net Contents - Specify the net contents of all retail containers for your product.

4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.

5. Location of the Directions - Indicate the Location of the use directions for your product.

6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.

6. EPA Use Only.

Moy. Regarding the missing submission from Ed Butts on 1,4 DMN tech 67727-E, he claims to have only made ONE 30 bmission. So probably the Two log-in book entries contain an error & diplication. Don't so wild looking for the 2nd package that probably doesn't exist worked on the 2/9/98 ppid one MOKE SURE DIANA Dense PIS. LOGS IT IN FIELD BOOK. PO & Also, I removed from your fileroom shelf the submission for 65175-20 215 198 from this up, and 9 Notrachen, If I can finish few other loose ends, I can get on the

PGR blanket tolerance things D

164

DP BARCODE: D242252

CASE: 062089

DATA PACKAGE RECORD

SUBMISSION: S536011

BEAN SHEET

DATE: 01/16/98 Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 165 NEW PROD-OC-MINOR CHG

CHEMICALS: 121701 Azadirachtin

14.0000%

ID#: 071038-G FORTUNE AZA TECHNICAL

COMPANY: 071038 FORTUNE BIOTECH LIMITED

PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL PM TEAM REVIEWER: RITA KUMAR 703-308-8291 ROOM: CS1 5TH FL

RECEIVED DATE: 08/12/97 DUE OUT DATE: 02/18/98

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 242252 EXPEDITE: N DATE SENT: 01/16/98 DATE RET.:

CHEMICAL: 121701 Azadirachtin

DP TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 06/15/98
DIV: BPPD / / / NEGOT DATE: / /
BRAN: BPPD-IO / / / PROJ DATE: / /
SECT: IO / / /

REVR :

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Freshteh: Please review ecotoxicity data for this new technical for azadirachtin. Registrant submitted a revised label and csf on 10/27/97, raising the amount of a.i. from 10% to 14%, but the manufacturing process was not changed.

MRID Numbers: 444285-01; -02; -03; -04. Thanks!

Rita

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC DATE OUT DUE BACK BRANCH/SECTION INS CSF LABEL 01/16/98 06/15/98 242246 BPPD-IO/IO Y Y Y 01/16/98 06/15/98 Y Y Y 242249 BPPD-IO/IO

(203) 256 9823 Butschme

he will send revised CSF & 8570 form for the tech application 67727 - E

for 67727-1 I advised him that protective gear will require opgrades to be relayed in upcoming letter. He wanted me to ensure that any label revision would create a label w/ fewer restrictions than on chlorpropham labels- I replied that the label will be based on the tox characteristics of his product without consideration of his marketing concerns. I'm sure he'll aduse us of any objections to our review. I also indicated That the application treyvency change (from 4x / season to "as needed) world trigger a requirement that they so smit an exposure presidue based just fication, citing Ray is comment on the rationale for our previous accesstance of lang term study data warrer requests. Butts contends that expense of treatment may well preclude users from applying more than 4 times: L sossested that if they do not wish to provide the rational, they should consider reinstating the 4 x application maximum.



# WASHINGTON, D.C. 20460

D-I-1-4, INC.
CO E.R. Butts International, INC
26 Sherman CT.
P. D. Box 764
Fair Field, CT 06430

PRODUCT NAME: 1,4-Sight Technical COMPANY NAME: D-I-1-4, INC.

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 67727-E EPA RECEIPT DATE: 12/3/97

Recycleurescychic

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions please contact Ray & joblal, Product Manager 91, at (103) 308-8260

Sincerely,

Frent End Processing Staff

Information Services Branch Information Resources & Services Division

E.R. BUTTS INTERNATIONAL, INC.

26 Sherman Court P.O. Box 764 Fairfield, CT 06430 Telephone: 203-256-0460

Fax: 203-256-0464

Via Federal Express - Standard

December 2, 1997

Ms. Denise Greenway (PM-90) Biopesticides and Pollution Prevention Division Office of Pesticide Programs **Environmental Protection Agency** Room 266A, Crystal Mall 2 1921Jefferson Davis Highway Arlington, VA 22202

Subject:

1,4SIGHT Technical – Aerosol Grade – Potato Dormancy Enhancer Application for Registration of a New Product Containing a Currently Registered Active Ingredient – 1,4-Dimethylnaphthalene

67727- E CSF says 94.7%; so to preposed latel 45 tamped one

Dear Denise:

D-I-1-4, Inc. would like to apply for registration of 1,4SIGHT Technical.

1,4SIGHT Technical is a new product containing the exact same active ingredient as the currently registered "1,4SIGHT - Aerosol Grade - Potato Sprout Inhibitor" (EPA Registration Number 67727-1). Both products contain 97.4% dimethylnaphthalene.

D-I-1-4, Inc. needs the 1,4SIGHT Technical label in order to import 1,4SIGHT into the United States in bulk for repackaging into smaller containers. This repackaging capability will allow D-I-1-4, Inc. to be more competitive in marketing its product.

form like small sizes & large ones call Ed Five (5) copies of the proposed revised labeling and one (1) copy each of the following are attached:

- Application for Pesticide Amendment (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8670-29)
- Data Matrix for 1,4Sight EPA Registration Number 67727-1

Should you have any questions regarding this application, please contact me. Thank you for your continued assistance.

Sincerely,

Edgar R. Butts, Ph.D.

Regulatory Consultant and Authorized Agent for D-I-1-4, Inc.

Attachments

CC: Mr. Darol Forsythe, President, D-I-1-4, Inc.

Mr. John Forsythe, General Manager, D-I-1-4, Inc.

This 67727-E CSF
motches orig CSF for
67727-R dated 12/21/97.
However, in 9/21/94 then
sobmitted a revised CSF shaving
arealy Did impurity. The
motch the latest CFS. Check >
-1 jacket to soe C. 1994 OSF was
possibly ever rejected. OSF was

The Comment

Say aid CT 08420

Vio Federal Express - Standard

December 2 1997

Ms. Danic - Maraway (PM-90)
Block I - Ima and Pollution Provention II - Local
Office of Pushciala Programs
John Local Protection Agency
From Local English Met 2
1927unceroun Davis Highs o

Application of Regional Control

on and control the 984, had special to a special of a spe

on 9121/94 they say the 'new' importing
wor recorded in MRID 43266961

See if ite in the matrix -it is

Jeff Herndons 10/7/94 review

seemingly okls new imports but notes
that other earlies submissions should be

RONE? IS IT REALLY MEEDED? it ! OPENING

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<b>≎EPA</b>	Environmenta	United States		X	1	OPP Identifier Number
		Application	n for Pesticio	de - Section	1	
1. Company/Product Number	or .		2. EPA F	Product Manager	3.	Proposed Classification
67727-			Denis	e Greenwa	У	X None Restricted
4. Company/Product (Name D-I-1-4, In		T Technic	PM#	91		
5. Name and Address of Ap D-I-1-4, In P.O. Box 86 Meridian, I	0		(b)(i), m			th FIFRA Section 3(c)(3) composition and labeling
Check if this	s is a new address		Produ	ct Name		
		*** 4	Section - I			
	oonse to Agency lette	r dated		Agency letter da "Me Too" Applic	cation.	
Notification - Explain	below.		XX	Other - Explain b	elow.	
			Section - II	ı		
1. Material This Product Wi		19, 7			*1	
Child-Resistant Packaging Yes No	Unit Packaging Yes No		Water Soluble Portion Yes X No	ackaging	2. Type of Contain  X Meta  X Plast  Glass	ic
* Certification must be submitted	If "Yes" Unit Packaging wg	No. per container	If "Yes" Package wgt	No. per container	Pape	r (Specify)
3. Location of Net Contents  X Label	Information Container		5.0,10.0, 1 and bul	30.0,	ocation of Label Direc	otions
6. Manner in Which Label is	Affixed to Product	X Lithogr Paper of Stencil	aph plued ed	Other	sizes as -1, da	ted 12/21/43 <
			Section - I	,	be right for th	is tech appl - see
1. Contact Point (Complete	items directly below	for identification	of individual to be	contacted, if ne	cessary, to process t	his application.)
Name Edgar R.	Butts, Ph.D		Title Agent a Co	nd REgula nsultant		one No. (Include Area Code) 256-0460
I certify that the state I acknowledge that as both under applicable	ny knowlinglly false o		all attachments the			6. Date Application Received (Stemped)
2. Signature	R Sutt	3	3. Title Agent	and Regu Consult	latory	
4. Typed Name Rdgar	R. Butts, P		5. Date	12/2/97		171

## PAPERMORK REDUCTION ACT MOTICE and INSTRUCTIONS

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4. Five copies of draft labeling;

5. Three copies of any data submitted; 6. Authorization letter where applicable;

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2. EPA Product Manager - If known, fill in the name and PW number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include

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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach

a separate page if additional space is needed.

SECTION TTT (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
 Type of Retail Container - Indicate type of container in which product will be marketed.

Location of Net Contents - Specify the net contents of all retail containers for your product.
 Size(s) of Metail Container - Specify the net contents of all retail containers for your product.

5. Location of Use Directions - Indicate the location of the use directions for your product.

6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.

6. EPA Use Orly

## **ŞEPA**

United States

## Environmental Protection Agency

Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-95

Certification with Respect to Citation of Data

EPA File Symbol/Registration Number 67727-Applicants Name and Address D-I-1-4, Inc. Product Name 1,4-SIGHT Technical P.O. Box 860 Meridian, ID 83680-0860 USA Date of Application December 2, 1997 NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27). 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.) 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study. I am the original submitter\*; or I have obtained the written permission of the original submitter for which is (insert name of chemical) (for multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study\* 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study; a. X I am the original data submitter\*; or I have obtained the written permission of the original data submitter for which is (insert name of chemical) (for multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study\*; or I have notified in writing the companies that (insert names of companies) (insert name of chemical) have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: Companies (for multiple (insert names of companies) (insert name of chemical) chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method\*). (Also, sign the General Offer Statement below.) (for multiple Companies (insert name of chemical) (insert names of companies) chemicals link the companies who are original data submitters with the appropriate chemical name that have submitted the studies which I have cited (Selective method\*). I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired. \* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

\*\*A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

\*\*Para R. Butts, Ph.D.

Name and Title Agent & Regulatory Consultant 12/2/97 Signature General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Regar R. Butts, Ph.D.

Name and TitleAgent & Regulatory ConsultarPete Signature 4 12/2/97

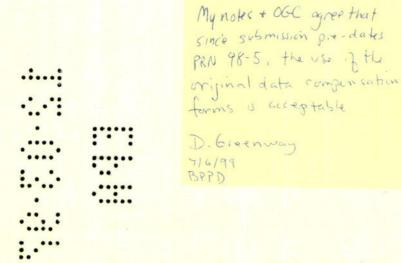
## Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."

form)

505

Prior PRN



## 1,4Sight Technical (1,4-Dimethylnaphthalene) - Data Matrix EPA Registration Number - 67727-1 Registrant - D-I-14, Inc. Date – December 2, 1997

## PRODUCT CHEMISTRY

151-10	PRODUCT IDENTIFICATION AND DISCLOSURE OF INGREDIENTS	٠
131-10	FRUDUCT IDENTIFICATION AND DISCLUSURE OF INGREDIENTS	

43082501 Butts, E. (1993) 1,4SIGHT: Product Identity and Disclosure of Ingredients. Unpublished study prepared by D-I-1-4, Inc. 10 pages.

## 151-11 DESCRIPTION OF BEGINNING MATERIALS AND MANUFACTURING PROCESS

43082502 Butts, E. (1993) 1,4SIGHT: Description of Beginning Materials and Manufacturing Process. Unpublished study prepared by D-I-1-4, Inc. 22 pages.

## 151-12 DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS

43082503 Butts, E. (1993) 1,4SIGHT: Discussion of the Formation of Impurities.
Unpublished study prepared by D-I-1-4, Inc. 8 pages.

## 151-13 ANALYSIS OF SAMPLES

- 43082504 Yeh, L. (1993) 1,4-DMN--Analysis of Samples: Lab Project Number: 4373-93-0300-AS. Unpublished study prepared by Ricerca, Inc. 232 pages.
- 43266801 Sato, T. (1993) Identification of Unknown #5 In 1,4-Dimethylnaphthalene (1,4-DMN): Analytical Report: Lab Project Number: 93-06-20. Unpublished study prepared by Sumikin Chemical Co. 33 pages.

## 151-15 CERTIFICATION OF INGREDIENT LIMITS

43082505 Butts, E. (1993) 1,4SIGHT: Certification of Ingredient Limits. Unpublished study prepared by D-I-1-4, Inc. 8 pages.

## 151-16 ANALYTICAL METHODS

- 43082504 Yeh, L. (1993) 1,4-DMN--Analysis of Samples: Lab Project Number: 4373-93-0300-AS. Unpublished study prepared by Ricerca, Inc. 232 pages.
- 43266801 Sato, T. (1993) Identification of Unknown #5 In 1,4-Dimethylnaphthalene (1,4-DMN): Analytical Report: Lab Project Number: 93-06-20. Unpublished study prepared by Sumikin Chemical Co. 33 pages.

## 151-17 PHYSICAL AND CHEMICAL PROPERTIES

43082506 Pelton, J. (1993) 1,4-DMN Batch H5510--Color, Physical State, Odor, Boiling Point, Specific Gravity, pH, Flammability, Impact Explodability, Viscosity: Lab Project Number: 4373-93-0226-AS. Unpublished study prepared by Ricerca, Inc. 53 pages.

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- 43082507 Lorence, P.; Vargyas, L.; Marsh, J. (1993) 1,4-DMN--Solubility: Lab Project Number: 4373-93-0250-AS. Unpublished study prepared by Ricerca, Inc. 57 pages.
- 43082508 Vargyas, L.; Marsh, J.; Yoder, S. (1993) 1,4-DMN--Vapor Pressure: Lab Project Number: 4373-93-0249-AS. Unpublished study prepared by Ricerca, Inc. 65 pages.
- 43266802 Pelton, J. (1994) 1,4-DMN Batch H5510-Corrosion Characteristics: Lab Project Number: 4373-93-0227-AS: 4373-93-0227-AS-001. Unpublished study prepared by Ricerca, Inc. 43 pages.
- 43082509 Sanders, J. (1993) 1,4-DMN--Stability: Lab Project Number: 4373-93-0247-AS. Unpublished study prepared by Ricerca, Inc. 40 pages.

## TOXICOLOGY

## 152-10 ACUTE ORAL TOXICITY

43082510 Johnson, W. (1993) Acute Oral Toxicity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rats: Final Report: Lab Project Number: L08456: SN6: SN7. Unpublished study prepared by IIT Research Institute. 51 pages.

## 152-11 ACUTE DERMAL TOXICITY

43082511 Johnson, W. (1993) Acute Dermal Toxicity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rabbits (Limit Test): Final Report: Lab Project Number: L08456: SN4. Unpublished study prepared by IIT Research Institute. 21 pages.

## 152-12 ACUTE INHALATION TOXICITY

43082512 Rajendran, N. (1993) Acute Inhalation Toxicity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rats: Final Report: Lab Project Number: L08456L001. Unpublished study prepared by IIT Research Institute. 29 pages.

#### 152-13 PRIMARY EYE IRRITATION

43082513 Johnson, W. (1993) Primary Eye Irritancy Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rabbits: Final Report: Lab Project Number: L08456: SN01. Unpublished study prepared by IIT Research Institute. 21 pages.

## 152-14 PRIMARY DERMAL IRRITATION

43082514 Johnson, W. (1993) Acute Dermal Irritancy/Corrosivity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rabbits: Final Report: Lab Project Number: L08456: SN2. Unpublished study prepared by IIT Research Institute. 19 pages.

## 152-15 HYPERSENSITIVITY STUDY

43082515 Johnson, W. (1993) Dermal Sensitization Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Guinea Pigs using the Modified Buehler Method: Final Report: Lab Project Number: L08456: SN05. Unpublished study prepared by 117 • Research Institute. 27 pages.

## 152-16 HYPERSENSITIVITY INCIDENTS

No hypersensitivity or allergic reactions have been observed during the use of 1,4-Dimethylnaphthalene

## 152-17 MUTAGENICITY

- 43082516 Lawlor, T. (1993) Mutagenicity Test on 1,4-Dimethylnaphthalene in the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test): Final Report: Lab Project Number: 15683-0-401. Unpublished study prepared by Hazleton Washington, Inc. 31 pages.
- 43082517 Ham, A. (1993) Genotoxicity Test on 1,4-Dimethylnaphthalene in the Assay for Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures: Final Report: Lab Project Number: 15683-0-447. Unpublished study prepared by Hazleton Washington, Inc. 25 pages.
- 43082518 Murli, H. (1993) Mutagenicity Test on 1,4-Dimethylnaphthalene in vivo Mouse Micronucleus Assay: Final Report: Lab Project Number: 15683-0-455. Unpublished study prepared by Hazleton Washington, Inc. 29 pages.

## 152-18 CELLULAR IMMUNE RESPONSE

Waiver granted based on very low levels of residue found in treated potatoes.

## 152-20 90-DAY FEEDING

Waiver granted based on very low levels of residue found in treated potatoes.

## 152-23 TERATOGENICITY

Waiver granted based on very low levels of residue found in treated potatoes.

## RESIDUE

### 153-3 MAGNITUDE OF THE RESIDUE IN STORED POTATOES

- 43266803 Wulf, L. (1993) Magnitude of Residue of 1,4-Dimethylnaphthalene on Potato Skin and Potato Pulp after Post-Harvest Fumigation: Interim Report: Lab Project Number: 93-002. Unpublished study prepared by Bioproducts, Inc.; Balivi Research Lab. 63 pages.
- 43594501 Wulf, L. (1994) Magnitude of Residue of 1,4-Dimethylnaphthalene on Potato Skin and Potato Pulp after Post-Harvest Fumigation: Final Report: Lab Project Number: 93-002. Unpublished study prepared by Bioproducts, Inc. and Balivi Research Labs. 107 pages.

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## **ECOLOGICAL EFFECTS**

## 154- 6 ACUTE AVIAN ORAL TOXICITY

43082519 Ahmed, S. (1993) Acute Oral LD(50) with Bobwhite Quail (*Colinus virginianus*) using 1,4-Dimethylnaphthalene (1,4-DMN): Lab Project Number: 93004. Unpublished study prepared by Genesis Laboratories, Inc. 38 pages.

## 154- 7 ACUTE AVIAN DIETARY TOXICITY

Waiver granted because use is indoor. No exposure is anticipated.

## 154-8 FISH TOXICITY - RAINBOW TROUT

43082520 Bettencourt, M. (1993) 1,4--Dimethylnaphthalene--Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions: Final Report: Lab Project Number: 93-10-4955: 13117.0693.6101.108. Unpublished study prepared by Springborn Laboratories, Inc. 69 pages.

## 154- 9 INVERTEBRATE TOXICITY - DAPHNIA

43082521 Putt, A. (1993) 1,4--Dimethylnaphthalene--Acute Toxicity to *Daphnids (Daphnia magna*) Under Flow-Through Conditions: Final Report: Lab Project Number: 93-10-4951: 13117.0693.6102.115. Unpublished study prepared by Springborn Laboratories, Inc. 85 pages.

## 154-10 NONTARGET PLANT TESTING

Waiver granted because use is indoor. No exposure is anticipated.

## 154-11 NONTARGET INSECT TESTING

Waiver granted because use is indoor. No exposure is anticipated.

## 154- HONEY BEE ACUTE CONTACT TOXICITY (LD<sub>50</sub>)

Waiver granted because use is indoor. No exposure is anticipated.

### 154- TOXICITY TO ESTUARINE AND MARINE - FISH

Waiver granted because use is indoor. No exposure is anticipated.

### 154- TOXICITY TO ESTUARINE AND MARINE - MOLLUSKS

Waiver granted because use is indoor. No exposure is anticipated.

## 154- TOXICITY TO ESTUARINE AND MARINE - SHRIMP

Waiver granted because use is indoor. No exposure is anticipated.

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there are label concerns w/ -1 Aerosol Grade - Potato Dormancy Enhancer

B	y Weight
Active Ingredient: 1,4-Dimethylnaphthalene*	94.7%
Other Ingredients:	5.3%
TOTAL	100.0%

## WARNING

Keep Out of Reach of Children

## PRECAUTIONARY STATEMENTS

## **Hazards to Humans and Domestic Animals**

## WARNING

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skirl, or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse.

## Statement of Practical Treatment

If in Eyes: Call a physician. Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. If Swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

If on the Skin: Wash skin with soap and large volumes of water.

## **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

## **Environmental Hazards**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See Directions for Use, Storage and Disposal, and Conditions of Sale on Reverse

Manufactured For: D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83860 USA Gallons do

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EPA Reg. Number 67727-EPA Est. Number 68738-JPN-001 Made in Japan **Revision - 971202** 

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<sup>\*</sup> Contains 7.9 pounds active ingredient per gallon.

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Only for formulation into a plant growth regulator for the following use: >

Potato dormancy enhancer on stored potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## STORAGE AND DISPOSAL

## STORAGE

vPest -

 Keep container closed. Do not contaminate water, food, or feed by storage or disposal. This product temporarily inhibits germination of seed potatoes.

## PESTICIDE DISPOSAL

 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

## **CONTAINER DISPOSAL**

 Do not reuse as a container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

## CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

## 1,4SIGHT Technical Aerosol Grade - Potato Dormancy Enhancer

В	y Weight
Active Ingredient: 1,4-Dimethylnaphthalene*	94.7%
Other Ingredients:	5.3%
TOTAL	100.0%

## WARNING

Keep Out of Reach of Children

## PRECAUTIONARY STATEMENTS

## Hazards to Humans and Domestic Animals

## WARNING

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse.

## Statement of Practical Treatment

If in <u>Eyes</u>: Call a physician. Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. If <u>Swallowed</u>: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

If on the Skin: Wash skin with soap and large volumes of water.

## **Emergency Information**

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

#### **Environmental Hazards**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

See Directions for Use, Storage and Disposal, and Conditions of Sale on Reverse

Net Contents: Gallons

Manufactured For: D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83860 USA EPA Reg. Number 67727-\_\_ EPA Est. Number 68758-JPN-001 Made in Japan Revision - 971202

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<sup>\*</sup> Contains 7.9 pounds active ingredient per gallon.

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Only for formulation into a plant growth regulator for the following use:

Potato dormancy enhancer on stored potatoes.

This product may be used to formulate products for any additional use(s) not listed on the 1,4Sight Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## STORAGE AND DISPOSAL

### STORAGE

 Keep container closed. Do not contaminate water, food, or feed by storage or disposal. This product temporarily inhibits germination of seed potatoes.

## PESTICIDE DISPOSAL

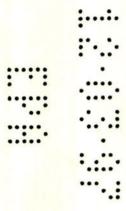
 Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

 Do not reuse as a container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

### CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



## 1,4SIGHT Technical Aerosol Grade - Potato Dormancy Enhancer

	By Weight
Active Ingredient: 1,4-Dimethylnaphthalene*	94.7%
Other Ingredients:	5.3%
TOTAL	100.0%

## WARNING

Keep Out of Reach of Children

## PRECAUTIONARY STATEMENTS

## **Hazards to Humans and Domestic Animals**

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If on the Skin: Wash skin with soap and large volumes of water.

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#### **Environmental Hazards**

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See Directions for Use, Storage and Disposal, and Conditions of Sale on Reverse

Net Contents: Gallons

Manufactured For: D-I-1-4, Inc. P.O. Box 860 Meridian, ID 83860 USA EPÅ Reg. Number 67727-\_ EPA Est. Number 68738-JPN-001 Made in Japan Revision - 971202

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<sup>\*</sup> Contains 7.9 pounds active ingredient per gallon.

## **DIRECTIONS FOR USE**

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Potato dormancy enhancer on stored potatoes.

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## STORAGE AND DISPOSAL

### STORAGE

 Keep container closed. Do not contaminate water, food, or feed by storage or disposal. This product temporarily inhibits germination of seed potatoes.

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 Do not reuse as a container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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